

## I

(Legislative acts)

## REGULATIONS

### 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 <sup>(1)</sup>,

Acting in accordance with the ordinary legislative procedure <sup>(2)</sup>,

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 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

<sup>(1)</sup> OJ C 283, 10.8.2018, p. 19.

<sup>(2)</sup> Position of the European Parliament of 14 February 2019 (not yet published in the Official Journal) and decision of the Council of 5 March 2019.

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 <sup>(3)</sup> 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.

<sup>(3)</sup> Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC (OJ L 218, 13.8.2008, p. 21).

- (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 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.
- (25) Where economic operators decide not to use the mutual recognition declaration, it should be for the competent authorities of the Member State of destination to make clearly defined requests for specific information that they consider to be necessary to assess the goods, with respect to the principle of proportionality.
- (26) The economic operator should be given appropriate time within which to submit documents or any other information requested by the competent authority of the Member State of destination, or to submit any arguments or comments in relation to the assessment of the goods in question.
- (27) Directive (EU) 2015/1535 of the European Parliament and of the Council<sup>(4)</sup> requires Member States to communicate to the Commission and to the other Member States any draft national technical regulation concerning any product, including any agricultural or fishery product, and a statement of the grounds on which the enactment of that regulation is necessary. It is necessary, however, to ensure that, following the adoption of such a national technical regulation, the principle of mutual recognition is correctly applied to specific goods in individual cases. This Regulation should lay down procedures for the application of the principle of mutual recognition in individual cases, for example, by requiring Member States to indicate the national technical rules on which the administrative decision is based and the legitimate public interest grounds that justify the application of that national technical rule with respect to a good that has been lawfully marketed in another Member State. The proportionality of the national technical rule is the basis for demonstrating the proportionality of the administrative decision that is based on that rule. However, the means by which the proportionality of the administrative decision is to be demonstrated should be determined on a case-by-case basis.
- (28) As administrative decisions restricting or denying market access for goods that are already lawfully marketed in another Member State should be exceptions to the fundamental principle of the free movement of goods, it is

<sup>(4)</sup> Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, 17.9.2015, p. 1).

necessary to ensure that such decisions observe the existing obligations that derive from the principle of mutual recognition. It is therefore appropriate to establish a clear procedure for determining whether goods are lawfully marketed in that other Member State and, if so, whether the legitimate public interests covered by the applicable national technical rule of the Member State of destination are adequately protected, in accordance with Article 36 TFEU and the case-law of the Court of Justice of the European Union. Such procedure should ensure that any administrative decisions that are taken are proportionate and respect the principle of mutual recognition and are in accordance with this Regulation.

- (29) Where a competent authority is assessing goods before deciding whether to restrict or deny market access, that authority should not be able to take decisions to suspend market access, except where rapid intervention is required to prevent harm to the safety or health of persons, to prevent harm to the environment, or to prevent the goods from being made available in cases where the making available of such goods is generally prohibited on grounds of public morality or public security, including, for example, the prevention of crime.
- (30) Regulation (EC) No 765/2008 of the European Parliament and of the Council <sup>(5)</sup> establishes a system of accreditation which ensures the mutual acceptance of the level of competence of conformity assessment bodies. The competent authorities of Member States should therefore not refuse to accept test reports and certificates issued by an accredited conformity assessment body on grounds related to the competence of that body. Furthermore, in order to avoid as far as possible the duplication of tests and procedures which have been already carried out in another Member State, Member States should not refuse to accept test reports and certificates issued by other conformity assessment bodies in accordance with Union law. Competent authorities should take due account of the content of the test reports or certificates submitted.
- (31) Directive 2001/95/EC of the European Parliament and of the Council <sup>(6)</sup> specifies that only safe products may be placed on the market and lays down the obligations of producers and distributors with respect to the safety of products. It entitles the competent authorities to ban any dangerous product with immediate effect or to ban products that could be dangerous temporarily for the period needed for the various safety evaluations, checks and controls. That Directive also describes the procedure for competent authorities to apply appropriate measures if products pose a risk, such as the measures referred to in points (b) to (f) of Article 8(1) of that Directive, and it also imposes an obligation on Member States to notify such measures to the Commission and the other Member States. Therefore, competent authorities should be able to continue applying that Directive and, in particular, points (b) to (f) of Article 8(1) and Article 8(3) of that Directive.
- (32) Regulation (EC) No 178/2002 of the European Parliament and of the Council <sup>(7)</sup> establishes, inter alia, a rapid alert system for the notification of direct or indirect risks to human health deriving from food or feed. It requires Member States to notify the Commission immediately, using the rapid alert system, of any measure they adopt which is aimed at restricting the placing on the market of food or feed, or withdrawing or recalling food or feed, for the purpose of protecting human health, and which requires rapid action. Competent authorities should be able to continue applying that Regulation and, in particular, Articles 50(3) and 54 of that Regulation.
- (33) Regulation (EU) 2017/625 of European Parliament and of the Council <sup>(8)</sup> establishes a harmonised Union framework for the organisation of official controls, and for the organisation of official activities other than

<sup>(5)</sup> Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

<sup>(6)</sup> Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (OJ L 11, 15.1.2002, p. 4).

<sup>(7)</sup> Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

<sup>(8)</sup> Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).

official controls, along the entire agri-food chain, taking into account the rules on official controls laid down in Regulation (EC) No 882/2004 of the European Parliament and of the Council <sup>(9)</sup> and in relevant Union sectoral legislation. Regulation (EU) 2017/625 lays down a specific procedure for ensuring that economic operators remedy situations of non-compliance with food and feed law, animal health rules or animal welfare rules. Competent authorities should be able to continue applying Regulation (EU) 2017/625 and, in particular, Article 138 thereof.

- (34) Regulation (EU) No 1306/2013 of the European Parliament and of the Council <sup>(10)</sup> establishes a harmonised Union framework for carrying out checks in respect of the obligations laid down in Regulation (EU) No 1308/2013 of the European Parliament and of the Council <sup>(11)</sup> in accordance with the criteria laid down in Regulation (EC) No 882/2004 and specifies that Member States shall ensure that any operator complying with those obligations is entitled to be covered by a system of checks. Competent authorities should be able to continue applying Regulation (EU) No 1306/2013 and, in particular, Article 90 thereof.
- (35) Any administrative decision taken by competent authorities of Member States pursuant to this Regulation should specify the remedies available to the economic operator, so that an economic operator is able, in accordance with national law, to appeal against the decision or bring proceedings before the competent national court or tribunal. The administrative decision should also refer to the possibility for economic operators to use the Internal Market Problem Solving Network (SOLVIT) and the problem-solving procedure provided for in this Regulation.
- (36) Effective solutions for economic operators wishing for a business friendly alternative when challenging administrative decisions restricting or denying market access are essential to ensure the correct and consistent application of the principle of mutual recognition. In order to guarantee such solutions, and to avoid legal costs, especially for small and medium-sized enterprises (SMEs), a non-judicial problem-solving procedure should be available for economic operators.
- (37) SOLVIT is a service provided by the national administration in each Member State that aims to find solutions for individuals and businesses when their rights have been breached by public authorities in another Member State. The principles governing the functioning of SOLVIT are set out in Commission Recommendation 2013/461/EU <sup>(12)</sup>, according to which each Member State is to provide for a SOLVIT Centre that has adequate human and financial resources to ensure that the SOLVIT Centre takes part in SOLVIT. The Commission should increase awareness about the existence and benefits of SOLVIT, especially among businesses.
- (38) SOLVIT is an effective non-judicial, problem-solving mechanism that is provided free of charge. It works under short deadlines and provides practical solutions to individuals and businesses when they are experiencing difficulties in the recognition of their Union rights by public authorities. Where the economic operator, the relevant SOLVIT Centre and the Member States involved all agree on the appropriate outcome, no further action should be required.
- (39) However, where the SOLVIT's informal approach fails, and doubts remain regarding the compatibility of the administrative decision with the principle of mutual recognition, the Commission should be empowered to look into the matter at the request of any of the SOLVIT Centres involved. Following its assessment, the Commission should issue an opinion to be communicated through the relevant SOLVIT Centre to the economic operator concerned and to the competent authorities, which should be taken into account during the SOLVIT procedure. The Commission's intervention should be subject to a time-limit of 45 working days, which should not include the time necessary for the Commission to receive any additional information and documents that it considers necessary. If the case is solved during this period, the Commission should not be required to issue an opinion. Such SOLVIT cases should be subject to a separate workflow in the SOLVIT database and should not be included in the regular SOLVIT statistics.

<sup>(9)</sup> Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ L 165, 30.4.2004, p. 1).

<sup>(10)</sup> Regulation (EU) No 1306/2013 of the European Parliament and of the Council of 17 December 2013 on the financing, management and monitoring of the common agricultural policy and repealing Council Regulations (EEC) No 352/78, (EC) No 165/94, (EC) No 2799/98, (EC) No 814/2000, (EC) No 1290/2005 and (EC) No 485/2008 (OJ L 347, 20.12.2013, p. 549).

<sup>(11)</sup> Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 (OJ L 347, 20.12.2013, p. 671).

<sup>(12)</sup> Commission Recommendation 2013/461/EU of 17 September 2013 on the principles governing SOLVIT (OJ L 249, 19.9.2013, p. 10).

- (40) The opinion of the Commission as regards an administrative decision restricting or denying market access should only address whether the administrative decision is compatible with the principle of mutual recognition and with the requirements of this Regulation. This is without prejudice to the Commission's powers under Article 258 TFEU and the Member States' obligation to comply with Union law, when addressing systemic problems identified as regards the application of the principle of mutual recognition.
- (41) It is important for the internal market for goods that businesses, in particular SMEs, can obtain reliable and specific information about the law in force in a given Member State. Product Contact Points should play an important role in facilitating communication between national authorities and economic operators by disseminating information about specific product rules and about how the principle of mutual recognition is applied in the territory of their Member State. Therefore, it is necessary to enhance the role of Product Contact Points as the principal providers of information on all product-related rules, including national technical rules covered by mutual recognition.
- (42) In order to facilitate the free movement of goods, Product Contact Points should provide, free of charge, a reasonable level of information on their national technical rules and the application of the principle of mutual recognition. Product Contact Points should be adequately equipped and resourced. In accordance with Regulation (EU) 2018/1724 of the European Parliament and of the Council <sup>(13)</sup> they should provide such information through a website and should be subject to the quality criteria set out in that Regulation. The tasks of Product Contact Points related to the provision of any such information, including electronic copies of, or online access to, the national technical rules, should be performed without prejudice to the national rules governing the distribution of national technical rules. Furthermore, Product Contact Points should not be required to provide copies of, or online access to, standards which are subject to the intellectual property rights of standardisation bodies or organisations.
- (43) Cooperation between competent authorities is essential for the smooth functioning of the principle of mutual recognition and for creating a mutual recognition culture. Product Contact Points and national competent authorities should therefore cooperate and exchange information and expertise in order to ensure the correct and consistent application of the principle of mutual recognition and this Regulation.
- (44) For the purposes of notifying administrative decisions restricting or denying market access, allowing communication between Product Contact Points and ensuring administrative cooperation, it is necessary to provide Member States with access to an information and communication system.
- (45) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council <sup>(14)</sup>.
- (46) Where, for the purposes of this Regulation, it is necessary to process personal data, such processing should be carried out in accordance with Union law on the protection of personal data. Any processing of personal data under this Regulation is subject to Regulation (EU) 2016/679 of the European Parliament and of the Council <sup>(15)</sup> or Regulation (EU) 2018/1725 of the European Parliament and of the Council <sup>(16)</sup>.
- (47) Reliable and efficient monitoring mechanisms should be established to provide information on the application of this Regulation and on its impact on the free movement of goods. Such mechanisms should not go beyond what is necessary to achieve these objectives.

<sup>(13)</sup> Regulation (EU) 2018/1724 of the European Parliament and of the Council of 2 October 2018 establishing a single digital gateway to provide access to information, to procedures and to assistance and problem-solving services and amending Regulation (EU) No 1024/2012 (OJ L 295, 21.11.2018, p. 1).

<sup>(14)</sup> Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

<sup>(15)</sup> Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

<sup>(16)</sup> Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

- (48) For the purposes of raising awareness about the principle of mutual recognition and ensuring that this Regulation is applied correctly and consistently, provision should be made for Union financing of awareness-raising campaigns, trainings, exchange of officials and other related activities aiming at enhancing and supporting trust and cooperation between competent authorities, Product Contact Points and economic operators.
- (49) In order to remedy the lack of accurate data related to the functioning of the principle of mutual recognition and its impact on the Single Market for goods, the Union should finance the collection of such data.
- (50) The financial interests of the Union should be protected through proportionate measures throughout the expenditure cycle, including the prevention, detection and investigation of irregularities, the recovery of funds lost, wrongly paid or incorrectly used and, where appropriate, administrative and financial penalties.
- (51) It is appropriate to defer the application of this Regulation in order to allow competent authorities and economic operators sufficient time to adapt to the requirements laid down herein.
- (52) The Commission should carry out an evaluation of this Regulation in light of the objectives that it pursues. The Commission should use the data collected on the functioning of the principle of mutual recognition and its impact on the single market for goods and information available in the information and communication system to evaluate this Regulation. The Commission should be able to request Member States to provide additional information necessary for its evaluation. Pursuant to point 22 of the Interinstitutional Agreement of 13 April 2016 on Better Law Making <sup>(17)</sup>, the evaluation of this Regulation, which should be based on efficiency, effectiveness, relevance, coherence and added value, should provide the basis for impact assessments of options for further action.
- (53) Since the objective of this Regulation, namely to ensure the smooth, consistent and correct application of the principle of mutual recognition, cannot be sufficiently achieved by the Member States but can rather, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective,

HAVE ADOPTED THIS REGULATION:

#### CHAPTER I

### GENERAL PROVISIONS

#### *Article 1*

#### **Subject matter**

1. The aim of this Regulation is to strengthen the functioning of the internal market by improving the application of the principle of mutual recognition and by removing unjustified barriers to trade.
2. This Regulation lays down rules and procedures concerning the application by Member States of the principle of mutual recognition in individual cases in relation to goods which are subject to Article 34 TFEU and which are lawfully marketed in another Member State, having regard to Article 36 TFEU and the case-law of the Court of Justice of the European Union.
3. This Regulation also provides for the establishment and maintenance of Product Contact Points in Member States and for cooperation and exchange of information in the context of the principle of mutual recognition.

#### *Article 2*

#### **Scope**

1. This Regulation applies to goods of any type, including agricultural products within the meaning of the second subparagraph of Article 38(1) TFEU, and to administrative decisions that have been taken or are to be taken by a competent authority of a Member State of destination in relation to any such goods that are lawfully marketed in another Member State, where the administrative decision meets the following criteria:
  - (a) the basis for the administrative decision is a national technical rule applicable in the Member State of destination; and
  - (b) the direct or indirect effect of the administrative decision is to restrict or deny market access in the Member State of destination.

<sup>(17)</sup> OJ L 123, 12.5.2016, p. 1.

Administrative decision includes any administrative step that is based on a national technical rule and that has the same or substantially the same legal effect as the effect referred to in point (b).

2. For the purposes of this Regulation, a 'national technical rule' is any provision of a law, regulation or other administrative provision of a Member State which has the following characteristics:

- (a) it covers goods or aspects of goods that are not the subject of harmonisation at Union level;
- (b) it either prohibits the making available of goods, or goods of a given type, on the market in that Member State, or it makes compliance with the provision compulsory, de facto or de jure, whenever goods, or goods of a given type, are made available on that market; and
- (c) it does at least one of the following:
  - (i) it lays down the characteristics required of goods or of goods of a given type, such as their levels of quality, performance or safety, or their dimensions, including the requirements applicable to those goods as regards the names under which they are sold, terminology, symbols, testing and test methods, packaging, marking or labelling and conformity assessment procedures;
  - (ii) for the purpose of protecting consumers or the environment, it imposes other requirements on goods or goods of a given type that affect the life-cycle of the goods after they have been made available on the market in that Member State, such as conditions of use, recycling, reuse or disposal, where such conditions can significantly influence either the composition or nature of those goods, or the making available of them on the market in that Member State.

3. Point (c)(i) of paragraph 2 of this Article also covers production methods and processes used in respect of agricultural products as referred to in the second subparagraph of Article 38(1) TFEU, and in respect of products intended for human or animal consumption, as well as production methods and processes relating to other products, where these have an effect on their characteristics.

4. A prior authorisation procedure does not itself constitute a national technical rule for the purposes of this Regulation, but a decision to refuse prior authorisation based on a national technical rule shall be considered to be an administrative decision to which this Regulation applies, if that decision fulfils the other requirements of the first subparagraph of paragraph 1.

5. This Regulation does not apply to:

- (a) decisions of a judicial nature taken by national courts or tribunals;
- (b) decisions of a judicial nature taken by law enforcement authorities in the course of the investigation or prosecution of a criminal offence as regards the terminology, symbols or any material reference to unconstitutional or criminal organisations or offences of a racist, discriminatory or xenophobic nature.

6. Articles 5 and 6 shall not affect the application of the following provisions:

- (a) points (b) to (f) of Article 8(1) and Article 8(3) of Directive 2001/95/EC;
- (b) point (a) of Article 50(3) and Article 54 of Regulation (EC) No 178/2002;
- (c) Article 90 of Regulation (EU) No 1306/2013; and
- (d) Article 138 of Regulation (EU) 2017/625.

7. This Regulation does not affect the obligation under Directive (EU) 2015/1535 to notify draft national technical regulations to the Commission and the Member States prior to their adoption.

### Article 3

#### Definitions

For the purposes of this Regulation, the following definitions apply:

- (1) 'lawfully marketed in another Member State' means that goods or goods of that type comply with the relevant rules applicable in that Member State or are not subject to any such rules in that Member State, and are made available to end users in that Member State;
- (2) 'making available on the market' means any supply of goods for distribution, consumption or use on the market within the territory of a Member State in the course of a commercial activity, whether in return for payment or free of charge;

- (3) 'restricting market access' means imposing conditions to be fulfilled before goods can be made available on the market in the Member State of destination, or conditions for keeping goods on that market, which in either case require the modification of one or more of the characteristics of those goods, as referred to in point (c)(i) of Article 2(2), or require the performance of additional testing;
- (4) 'denying market access' means any of the following:
  - (a) prohibiting goods from being made available on the market in the Member State of destination or from being kept on that market; or
  - (b) requiring the withdrawal or recall of those goods from that market;
- (5) 'withdrawal' means any measure aimed at preventing goods in the supply chain from being made available on the market;
- (6) 'recall' means any measure aimed at achieving the return of goods that have already been made available to the end user;
- (7) 'prior authorisation procedure' means an administrative procedure under the law of a Member State whereby the competent authority of that Member State is required, on the basis of an application by an economic operator, to give its formal approval before goods may be made available on the market in that Member State;
- (8) 'producer' means:
  - (a) any natural or legal person who manufactures goods or has goods designed or manufactured, or who produces goods which were not the result of a manufacturing process, including agricultural products, and markets them under that person's name or trademark,
  - (b) any natural or legal person who modifies goods already lawfully marketed in a Member State in a way that might affect compliance with the relevant rules applicable in that Member State, or
  - (c) any other natural or legal person who, by putting its name, trademark or other distinguishing feature on goods or on the documents that accompany those goods, presents itself as the producer of those goods;
- (9) 'authorised representative' means any natural or legal person established within the Union who has received a written mandate from a producer to act on that producer's behalf with regard to the making available of goods on the market in question;
- (10) 'importer' means any natural or legal person established within the Union who makes goods from a third country available on the Union market for the first time;
- (11) 'distributor' means any natural or legal person in the supply chain, other than the producer or the importer, who makes goods available on the market in a Member State;
- (12) 'economic operator' means any of the following in relation to goods: the producer, the authorised representative, the importer or the distributor;
- (13) 'end user' means any natural or legal person residing or established in the Union, to whom the goods have been made available or are being made available, either as a consumer outside of any trade, business, craft or profession or as a professional end user in the course of its industrial or professional activities;
- (14) 'legitimate public interest grounds' means any of the grounds set out in Article 36 TFEU or any other overriding reasons of public interest;
- (15) 'conformity assessment body' means a conformity assessment body as defined in point 13 of Article 2 of Regulation (EC) No 765/2008.

## CHAPTER II

### PROCEDURES CONCERNING APPLICATION OF THE PRINCIPLE OF MUTUAL RECOGNITION IN INDIVIDUAL CASES

#### Article 4

#### **Mutual recognition declaration**

1. The producer of goods, or of goods of a given type, that are being made or are to be made available on the market in the Member State of destination may draw up a voluntary declaration of lawful marketing of goods for the purposes of mutual recognition ('mutual recognition declaration') in order to demonstrate to the competent authorities of the Member State of destination that the goods, or the goods of that type, are lawfully marketed in another Member State.

The producer may mandate its authorised representative to draw up the mutual recognition declaration on its behalf.

The mutual recognition declaration shall follow the structure set out in Part I and Part II of the Annex and shall contain all the information specified therein.

The producer or its authorised representative, where mandated to do so, may fill in the mutual recognition declaration with only the information set out in Part I of the Annex. In such case the information set out in Part II of the Annex shall be filled in by the importer or by the distributor.

Alternatively, both parts of the mutual recognition declaration may be drawn up by the importer or by the distributor, provided that the signatory can supply the evidence referred to in point (a) of Article 5(4).

The mutual recognition declaration shall be drawn up in one of the official languages of the Union. Where that language is not the language required by the Member State of destination, the economic operator shall translate the mutual recognition declaration into a language required by the Member State of destination.

2. Economic operators who sign the mutual recognition declaration or a part of it shall be responsible for the content and accuracy of the information that they provide in the mutual recognition declaration, including the correctness of the information they translate. For the purposes of this paragraph, economic operators shall be liable in accordance with national laws.

3. Economic operators shall ensure that the mutual recognition declaration is kept up to date at all times, reflecting any changes in the information that they have provided in the mutual recognition declaration.

4. The mutual recognition declaration may be supplied to the competent authority of the Member State of destination for the purposes of an assessment to be carried out under Article 5. It may be supplied either in paper form or by electronic means or be made available online in accordance with the requirements of the Member State of destination.

5. Where economic operators make the mutual recognition declaration available online, the following conditions apply:

(a) the type of goods or the series to which the mutual recognition declaration applies shall be easily identifiable; and

(b) the technical means used shall ensure easy navigation and shall be monitored to ensure the availability of, and access to, the mutual recognition declaration.

6. Where the goods for which the mutual recognition declaration is being supplied are also subject to a Union act requiring an EU declaration of conformity, the mutual recognition declaration may be attached to the EU declaration of conformity.

#### *Article 5*

#### **Assessment of goods**

1. Where a competent authority of the Member State of destination intends to assess goods subject to this Regulation to establish whether the goods or goods of that type are lawfully marketed in another Member State, and, if so, whether the legitimate public interests covered by the applicable national technical rule of the Member State of destination are adequately protected, having regard to the characteristics of the goods in question, it shall contact the economic operator concerned without delay.

2. When entering into contact with the economic operator concerned, the competent authority of the Member State of destination shall inform the economic operator of the assessment, indicating the goods that are subject to that assessment and specifying the applicable national technical rule or prior authorisation procedure. The competent authority of the Member State of destination shall also inform the economic operator of the possibility of supplying a mutual recognition declaration in accordance with Article 4 for the purposes of that assessment.

3. The economic operator shall be allowed to make the goods available on the market in the Member State of destination while the competent authority carries out the assessment under paragraph 1 of this Article, and may continue to do so unless the economic operator receives an administrative decision restricting or denying market access for those goods. This paragraph shall not apply where the assessment is carried out in the framework of a prior authorisation procedure, or where the competent authority temporarily suspends the making available on the market of the goods that are subject to that assessment in accordance with Article 6.

4. If a mutual recognition declaration is supplied to a competent authority of the Member State of destination in accordance with Article 4, then for the purposes of the assessment under paragraph 1 of this Article:
- the mutual recognition declaration, together with supporting evidence necessary to verify the information contained in it that was provided in response to a request by the competent authority, shall be accepted by the competent authority as sufficient to demonstrate that the goods are lawfully marketed in another Member State; and
  - the competent authority shall not require any other information or documentation from any economic operator for the purpose of demonstrating that the goods are lawfully marketed in another Member State.
5. If a mutual recognition declaration is not supplied to a competent authority of the Member State of destination in accordance with Article 4, then for the purposes of the assessment under paragraph 1 of this Article, the competent authority may request the economic operators concerned to provide documentation and information that is necessary for that assessment concerning the following:
- the characteristics of the goods or type of goods in question; and
  - lawful marketing of the goods in another Member State.
6. The economic operator concerned shall be allowed at least 15 working days following the request of the competent authority of the Member State of destination in which to submit the documents and information referred to in point (a) of paragraph 4 or in paragraph 5, or to submit any arguments or comments that the economic operator might have.
7. For the purposes of the assessment under paragraph 1 of this Article, the competent authority of the Member State of destination, in accordance with Article 10(3), may contact the competent authorities or the Product Contact Points of the Member State in which an economic operator claims to be lawfully marketing its goods, if the competent authority needs to verify any information provided by the economic operator.
8. In carrying out the assessment under paragraph 1, the competent authorities of Member States of destination shall take due account of the content of test reports or certificates issued by a conformity assessment body that have been provided by any economic operator as part of the assessment. The competent authorities of Member States of destination shall not refuse test reports or certificates that were issued by a conformity assessment body accredited for the appropriate field of conformity assessment activity in accordance with Regulation (EC) No 765/2008 on grounds related to the competence of that body.
9. Where, on completion of an assessment under paragraph 1 of this Article, the competent authority of a Member State of destination takes an administrative decision with respect to the goods that it has assessed, it shall notify that administrative decision without delay to the economic operator referred to in paragraph 1 of this Article. The competent authority shall also notify that administrative decision to the Commission and to the other Member States no later than 20 working days after it took the decision. For that purpose, it shall use the system referred to in Article 11.
10. The administrative decision referred to in paragraph 9 shall set out the reasons for the decision in a manner that is sufficiently detailed and reasoned to facilitate an assessment of its compatibility with the principle of mutual recognition and with the requirements of this Regulation.
11. In particular, the following information shall be included in the administrative decision referred to in paragraph 9:
- the national technical rule on which the administrative decision is based;
  - the legitimate public interest grounds justifying the application of the national technical rule on which the administrative decision is based;
  - the technical or scientific evidence that the competent authority of the Member State of destination considered, including, where applicable, any relevant changes in the state of the art that have occurred since the national technical rule came into force;
  - a summary of the arguments put forward by the economic operator concerned that are relevant for the assessment under paragraph 1, if any;
  - the evidence demonstrating that the administrative decision is appropriate for the purpose of achieving the objective pursued and that the administrative decision does not go beyond what is necessary in order to attain that objective.
12. The administrative decision referred to in paragraph 9 of this Article shall specify the remedies available under the national law of the Member State of destination and the time limits applicable to those remedies. It shall also include a reference to the possibility for economic operators to use SOLVIT and the procedure under Article 8.
13. The administrative decision referred to in paragraph 9 shall not take effect before it has been notified to the economic operator concerned under that paragraph.

*Article 6***Temporary suspension of market access**

1. When the competent authority of a Member State is carrying out an assessment of goods pursuant to Article 5, it may temporarily suspend the making available of those goods on the market in that Member State only if:
  - (a) under normal or reasonably foreseeable conditions of use, the goods pose a serious risk to safety or health of persons or to the environment, including one where the effects are not immediate, which requires rapid intervention by the competent authority; or
  - (b) the making available of the goods, or of goods of that type, on the market in that Member State is generally prohibited in that Member State on grounds of public morality or public security.
2. The competent authority of the Member State shall immediately notify the economic operator concerned, the Commission and the other Member States of any temporary suspension pursuant to paragraph 1 of this Article. The notification to the Commission and the other Member States shall be made by means of the system referred to in Article 11. In cases falling within point (a) of paragraph 1 of this Article, the notification shall be accompanied by a detailed technical or scientific justification demonstrating why the case falls within the scope of that point.

*Article 7***Notification through RAPEX or RASFF**

If the administrative decision referred to in Article 5 or the temporary suspension referred to in Article 6 is also a measure which is to be notified through the Rapid Information Exchange System (RAPEX) in accordance with Directive 2001/95/EC or through the Rapid Alert System for Food and Feed (RASFF) in accordance with Regulation (EC) No 178/2002, a separate notification to the Commission and the other Member States under this Regulation shall not be required, provided that the following conditions are met:

- (a) the RAPEX or RASFF notification indicates that the notification of the measure also serves as a notification under this Regulation; and
- (b) the supporting evidence required for the administrative decision under Article 5 or for the temporary suspension under Article 6 is included with the RAPEX or RASFF notification.

*Article 8***Problem-solving procedure**

1. Where an economic operator affected by an administrative decision has submitted it to SOLVIT and where, during the SOLVIT procedure, the Home Centre or the Lead Centre requests the Commission to give an opinion in order to assist in solving the case, the Home Centre and the Lead Centre shall provide the Commission with all relevant documents relating to the administrative decision concerned.
2. After receiving the request referred to in paragraph 1, the Commission shall assess whether the administrative decision is compatible with the principle of mutual recognition and with the requirements of this Regulation.
3. For the purposes of the assessment referred to in paragraph 2 of this Article, the Commission shall consider the administrative decision notified in accordance with Article 5(9) and the documents and information provided within the SOLVIT procedure. Where additional information or documents are needed for the purposes of the assessment referred to in paragraph 2 of this Article, the Commission shall, without undue delay, request the relevant SOLVIT Centre to enter into communication with the economic operator concerned or with the competent authorities which took the administrative decision, for the purpose of obtaining such additional information or documents.
4. Within 45 working days of receipt of the request referred to in paragraph 1, the Commission shall complete its assessment and issue an opinion. Where appropriate, the Commission's opinion shall identify any concerns that should be addressed in the SOLVIT case or shall make recommendations to assist in solving the case. The 45 working day period does not include the time necessary for the Commission to receive the additional information and documents as provided for in paragraph 3.
5. Where the Commission has been informed that the case is solved during the assessment referred to in paragraph 2, the Commission shall not be required to issue an opinion.
6. The Commission's opinion shall be communicated through the relevant SOLVIT Centre to the economic operator concerned and to the relevant competent authorities. That opinion shall be notified by the Commission to all Member States by means of the system referred to in Article 11. The opinion shall be taken into account during the SOLVIT procedure referred to in paragraph 1 of this Article.

## CHAPTER III

**ADMINISTRATIVE COOPERATION, MONITORING AND COMMUNICATION***Article 9***Tasks of the Product Contact Points**

1. Member States shall designate and maintain Product Contact Points on their territory and shall ensure that their Product Contact Points have sufficient powers and adequate resources for the proper performance of their tasks. They shall ensure that Product Contact Points deliver their services in accordance with Regulation (EU) 2018/1724.
2. Product Contact Points shall provide the following information online:
  - (a) information on the principle of mutual recognition and the application of this Regulation in the territory of their Member State, including information on the procedure set out in Article 5;
  - (b) the contact details, by means of which the competent authorities within that Member State may be contacted directly, including the particulars of the authorities responsible for supervising the implementation of the national technical rules applicable in the territory of their Member State;
  - (c) the remedies and procedures available in the territory of their Member State in the event of a dispute between the competent authority and an economic operator, including the procedure set out in Article 8.
3. Where necessary to complement the information provided online under paragraph 2, Product Contact Points shall provide, at the request of an economic operator or a competent authority of another Member State, any useful information, such as electronic copies of, or online access to, the national technical rules and national administrative procedures applicable to specific goods or goods of a specific type in the territory in which the Product Contact Point is established or information on whether those goods or goods of that type are subject to prior authorisation under national law.
4. Product Contact Points shall respond within 15 working days of receiving any request under paragraph 3.
5. Product Contact Points shall not charge any fee for the provision of the information under paragraph 3.

*Article 10***Administrative cooperation**

1. The Commission shall provide for and ensure efficient cooperation among the competent authorities and the Product Contact Points of the various Member States through the following activities:
  - (a) facilitating and coordinating the exchange and collection of information and best practices with regard to the application of the principle of mutual recognition;
  - (b) supporting the functioning of the Product Contact Points and enhancing their cross-border cooperation;
  - (c) facilitating and coordinating the exchange of officials among Member States and the organisation of common training and awareness raising programmes for authorities and businesses.
2. Member States shall ensure that their competent authorities and Product Contact Points participate in the activities referred to in paragraph 1.
3. Upon a request by a competent authority of the Member State of destination pursuant to Article 5(7), the competent authorities in the Member State in which an economic operator claims to be lawfully marketing its goods shall provide the competent authority of the Member State of destination within 15 working days with any information relevant for verifying data and documents supplied by the economic operator during the assessment under Article 5 relating to those goods. The Product Contact Points may be used to facilitate contacts between the relevant competent authorities in accordance with the time limit for providing the requested information set out in Article 9(4).

*Article 11***Information and communication system**

1. For the purposes of Articles 5, 6 and 10 of this Regulation, the information and communication system set out in Article 23 of Regulation (EC) No 765/2008 shall be used, except as provided in Article 7 of this Regulation.
2. The Commission shall adopt implementing acts specifying the details and functionalities of the system referred to in paragraph 1 of this Article for the purposes of this Regulation. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 15(2).

## CHAPTER IV

## FINANCING

## Article 12

**Financing of activities in support of this Regulation**

1. The Union may finance the following activities in support of this Regulation:
  - (a) awareness-raising campaigns;
  - (b) education and training;
  - (c) exchange of officials and of best practices;
  - (d) cooperation among Product Contact Points and competent authorities, and the technical and logistic support for this cooperation;
  - (e) the collection of data related to the functioning of the principle of mutual recognition and its impact on the Single Market for goods.
2. The Union's financial assistance with respect to activities in support of this Regulation shall be implemented in accordance with Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council <sup>(18)</sup>, either directly or by entrusting budget implementation tasks to the entities listed in point (c) of Article 62(1) of that Regulation.
3. The appropriations allocated to activities referred to in this Regulation shall be determined each year by the budgetary authority within the limits of the financial framework in force.

## Article 13

**Protection of the financial interests of the Union**

1. The Commission shall take appropriate measures to ensure that, when activities financed under this Regulation are implemented, the financial interests of the Union are protected by the application of preventive measures against fraud, corruption and any other illegal activities, by effective checks and, if irregularities are detected, by the recovery of the amounts wrongly paid and, where appropriate, by effective, proportionate and dissuasive administrative and financial penalties.
2. The Commission or its representatives and the Court of Auditors shall have the power of audit, on the basis of documents and of on-the-spot inspections, over all grant beneficiaries, contractors and subcontractors who have received Union funds under this Regulation.
3. The European Anti-Fraud Office (OLAF) may carry out investigations, including on-the-spot checks and inspections, in accordance with the provisions and procedures laid down in Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council <sup>(19)</sup> and Council Regulation (Euratom, EC) No 2185/96 <sup>(20)</sup> with a view to establishing whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the Union in connection with a grant agreement or grant decision or a contract funded under this Regulation.
4. Without prejudice to paragraphs 1, 2 and 3, cooperation agreements with third countries and with international organisations, contracts, grant agreements and grant decisions, resulting from the implementation of this Regulation shall contain provisions expressly empowering the Commission, the Court of Auditors and OLAF to conduct such audits and investigations, in accordance with their respective competences.

<sup>(18)</sup> Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193, 30.7.2018, p. 1).

<sup>(19)</sup> Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.9.2013, p. 1).

<sup>(20)</sup> Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15.11.1996, p. 2.).

## CHAPTER V

**EVALUATION AND COMMITTEE PROCEDURE***Article 14***Evaluation**

1. By 20 April 2025, and every four years thereafter, the Commission shall carry out an evaluation of this Regulation in light of the objectives that it pursues and shall submit a report thereon to the European Parliament, to the Council and to the European Economic and Social Committee.
2. For the purposes of paragraph 1 of this Article, the Commission shall use the information available in the system referred to in Article 11 and any data collected in the course of activities referred to in point (e) of Article 12(1). The Commission may also ask Member States to submit any relevant information for evaluating the free movement of goods lawfully marketed in another Member State or for evaluating the effectiveness of this Regulation, as well as an assessment of the functioning of the Product Contact Points.

*Article 15***Committee procedure**

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

## CHAPTER VI

**FINAL PROVISIONS***Article 16***Repeal**

Regulation (EC) No 764/2008 is repealed with effect from 19 April 2020.

References to the repealed Regulation shall be construed as references to this Regulation.

*Article 17***Entry into force and application**

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 19 April 2020.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 19 March 2019.

*For the European Parliament*  
*The President*  
A. TAJANI

*For the Council*  
*The President*  
G. CIAMBA

## ANNEX

Mutual recognition declaration for the purposes of Article 4 of Regulation (EU) 2019/515 of the European Parliament and of the Council <sup>(1)</sup>

## Part I

1. Unique identifier for the goods or type of goods: ... [Note: insert the goods identification number or other reference marker that uniquely identifies the goods or type of goods]
2. Name and address of the economic operator: ... [Note: insert the name and address of the signatory of Part I of the mutual recognition declaration: the producer and, where applicable, its authorised representative, or the importer, or the distributor]
3. Description of the goods or type of goods subject of the mutual recognition declaration: ... [Note: the description should be sufficient to enable the goods to be identified for traceability reasons. It may be accompanied by a photograph, where appropriate]
4. Declaration and information on the lawfulness of the marketing of the goods or that type of goods
  - 4.1. The goods or type of goods described above, including their characteristics, comply with the following rules applicable in ... [Note: identify the Member State in which the goods or that type of goods are claimed to be lawfully marketed]: ... [Note: insert the title and official publication reference, in each case, of the relevant rules applicable in that Member State and reference of the authorisation decision if the goods were subject to a prior authorisation procedure],  
  
or  
  
the goods or type of goods described above are not subject to any relevant rules in ... [Note: identify the Member State in which the goods or that type of goods are claimed to be lawfully marketed].
  - 4.2. Reference of the conformity assessment procedure applicable to the goods or that type of goods, or reference of test reports for any tests performed by a conformity assessment body, including the name and address of that body (if such procedure was carried out or if such tests were performed): ...
5. Any additional information considered relevant to an assessment of whether the goods or that type of goods are lawfully marketed in the Member State indicated in point 4.1: ...
6. This part of the mutual recognition declaration has been drawn up under the sole responsibility of the economic operator identified under point 2.

Signed for and on behalf of:

(place and date):

(name, function) (signature):

## Part II

7. Declaration and information on the marketing of the goods or that type of goods
  - 7.1. The goods or that type of goods described in Part I are made available to end users on the market in the Member State indicated in point 4.1.
  - 7.2. Information that the goods or that type of goods are made available to the end users in the Member State indicated in point 4.1, including details of the date of when the goods were first made available to end users on the market in that Member State: ...
8. Any additional information considered relevant to an assessment of whether the goods or that type of goods are lawfully marketed in the Member State indicated in point 4.1: ...

<sup>(1)</sup> 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 (OJ L 91, 29.3.2019, p. 1).

