



**Council of the European Union**  
General Secretariat

Directorate-General Economic Affairs and Competitiveness - ECOMP  
Directorate Competitiveness  
Unit 3A - Internal Market, Consumer Policy, Better Regulation

Brussels, 28 November 2018

**Ms Anneleen VAN BOSSUYT**

Chair, European Parliament Committee on Internal Market and Consumer Protection  
European Parliament  
Rue Wiertz 60, B-1047 Brussels  
Belgium

Subject: Proposal for a Regulation of the European Parliament and of the Council on the mutual recognition of goods lawfully marketed in another Member State

Dear Ms VAN BOSSUYT,

Following the informal meeting between the representatives of the three institutions, a draft overall compromise package was agreed today by the Permanent Representatives' Committee.

I am therefore now in a position to confirm that, should the European Parliament adopt its position at first reading in accordance with Article 294(3) of the Treaty on the Functioning of the European Union (TFEU) in the form as set out in the compromise package contained in the Annex to this letter (subject to revision by the lawyer linguists of both institutions), the Council would, in accordance with Article 294(4) TFEU, approve the European Parliament's position and the act shall be adopted in the wording which corresponds to the European Parliament's position.

On behalf of the Council I also wish to thank you for your close cooperation which should enable us to reach agreement on this dossier at first reading.

Yours sincerely,

**Mr Thomas OBERREITER**  
Chairman of the Permanent Representatives  
Committee (Part 1)

Copy to: **Ms Elżbieta BIENKOWSKA**, Member of the European Commission  
**Mr Ivan ŠTEFANEC**, Rapporteur

**Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the mutual recognition of goods lawfully marketed in another Member State  
(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,

Whereas:

- (1) The internal market comprises an area without internal frontiers in which the free movement of goods is ensured in accordance with the provisions of 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. Free movement of goods is ensured in the internal market by harmonisation of rules at Union level setting 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.
- (1a) A well-functioning principle of mutual recognition is an essential complement to harmonisation at EU level, especially taking into consideration that many products have both harmonised and non-harmonised aspects.

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<sup>1</sup> OJ C , , p . .

- (2) 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 a certain aspect of goods, a Member State's competent authority applies national rules to goods of that type 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 lawfully marketed in another Member State could be contrary to Articles 34 and 36 of the Treaty even if the rules apply without distinction to all goods.
- (3) 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 the goods have been produced, including the ones not obtained through manufacturing process, in accordance with different technical rules. But the principle is not absolute. Member States can oppose the marketing of goods lawfully marketed elsewhere, when such restrictions are justified on the grounds set out in Article 36 of the Treaty or on the basis of other overriding reasons of public interest, recognised by the ECJ jurisprudence in relation to the free movement of goods, and which in either case are proportionate to the aim pursued. This regulation imposes the obligation to clearly justify why market access is refused.
- (4) The concept of overriding reasons of public interest is an evolving concept developed by the Court of Justice in its case-law in relation to Articles 34 and 36 of the Treaty. Where legitimate differences exist from one Member State to another, such overriding reasons may justify the application of national rules by the competent authorities. However, administrative decisions need to be always duly justified, legitimate, appropriate and in respect with the principle of proportionality and the competent authority has to make the least restrictive decision possible. With the aim of improving the functioning of the internal market for goods, the national rules should be fit for purpose and not create disproportionate non-tariff barriers. Furthermore, administrative decisions restricting or denying market access in respect of goods 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 that goods in that Member State fulfil that objective. In order to assist Member States, the Commission should provide non-binding guidance reviewing the case law on the concept of overriding reasons of public interest and on how to apply the principle of mutual recognition. Competent authorities should have the opportunity to provide contributions and deliver feedback on the guidance.

- (5) Regulation (EC) No 764/2008<sup>2</sup> was adopted in order to facilitate the application of the mutual recognition principle, 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 mutual recognition principle. The evaluation carried out between 2014 and 2016 showed that the principle does not function as it should and Regulation (EC) No 764/2008 has had limited effect in facilitating its application. The tools and procedural guarantees put in place by Regulation (EC) No 764/2008 failed in their aim of improving the application of the mutual recognition principle. 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 mutual recognition is barely known or used by economic operators. Within the network, national authorities do not cooperate sufficiently. The requirement to notify administrative decisions denying or restricting market access is complied with rarely. As a result, obstacles to free movement of goods in the internal market remain.
- (6) In December 2013, the conclusions on the Single Market Policy adopted by 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 the cases where the functioning of the mutual recognition principle 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 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 the restriction is justified and proportionate. It ensures that existing rights and obligations deriving from the mutual recognition principle are observed, by both economic operators and national authorities.
- (8) This Regulation should not prejudice further harmonisation of conditions for the marketing of goods, where appropriate, with a view to improving the functioning of the internal market.

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<sup>2</sup> OJ, L 218, 13.8.2008, p.21

- (9) Trade barriers may also result from other types of measures falling under the scope of Articles 34 and 36 of the Treaty. Those measures may, for example, include 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.
- (10) National technical rules are sometimes given effect in a Member State by means of a prior authorisation procedure, under which formal approval must 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 free movement of goods within the internal market, such a procedure must pursue a public interest objective recognised by Union law, and it must be proportionate and non-discriminatory. The compliance of such a procedure with Union law is assessed in the light of the considerations set out in the case-law of the Court of Justice. As a result, administrative decisions denying or restricting 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 intended administrative decision to reject the application on the basis of a technical rule applicable in that Member State should 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.
- (11) 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) of the Treaty. To help 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.
- (12) It is important to clarify that the term 'producer' includes not only the manufacturer of goods, but also the person who produces goods which were not obtained by a manufacturing process, including agricultural products, as well as the person who presents himself as the producer of goods.

- (13) 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 of another Member State, and decisions of national courts or tribunals applying penalties, should be excluded from the scope of this Regulation.
- (14) 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 as lawfully marketed in another Member State, the goods need to comply with the relevant rules applicable in that Member State, and to be made available to end users in that Member State.
- (14a) 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.
- (15) 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, while preventing national authorities from obtaining the information necessary for assessing the goods in a timely manner. This may inhibit application of the mutual recognition principle. 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 process of self-declaration, which should provide 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 the voluntary declaration does not prevent national authorities from taking an administrative decision restricting market access, on the condition that such a decision is proportionate, justified and respects the mutual recognition principle and this Regulation.
- (16) 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 for filling in the information in the mutual recognition declaration as he knows the goods best and is in a possession of the evidence necessary for verification of the information contained in the declaration. The producer should be able to mandate his authorised representative to draw up such declaration on his behalf and under his responsibility. However, where an economic operator is able to provide in the declaration only the information on the lawfulness of the marketing of the goods, it should be possible for another economic operator to provide the information that the goods are being made available to end users in the relevant Member State, provided that this economic operator takes the responsibility for the information he filled into the mutual recognition declaration and is able to supply the necessary evidence to verify it.

- (17) The mutual recognition declaration should continue to give accurate and complete information on the goods at any point in the future. The declaration should therefore be kept up to date in order to reflect changes, for example changes in the relevant technical rules.
- (18) 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.
- (19) It is important to ensure that the mutual recognition declaration is filled in truthfully and accurately. It is therefore necessary to provide for economic operators to be responsible for the information provided by them in the declaration.
- (20) In order to enhance the efficiency and competitiveness of businesses operating in the non-harmonised area, it should be possible to benefit from new information technologies for the purposes of facilitating the provision of the mutual recognition declaration. Therefore, economic operators should be able to make their declaration publicly available online provided that it would be easily accessible and in a reliable format.
- (20a) The Commission should ensure that a template for the mutual recognition declaration and relevant guidelines to complete the declaration are made available on the Single Digital Gateway in all of the official languages of the Union.
- (20b) *deleted*
- (21) 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, economic operators are required to draw up an EU declaration of conformity to demonstrate compliance with that legislation, it should be permissible for the mutual recognition declaration under this Regulation to be attached to the EU declaration of conformity.
- (22) Where economic operators decide not to make use of the mutual recognition declaration, it should be for the competent authorities of the Member State to request specific and clearly defined information that they consider necessary for the assessment of the goods in respect of the principle of proportionality.
- (22a) 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 present any comments or arguments in relation to the assessment of the goods in question.

- (23) Directive (EU) 2015/1535 of the European Parliament and of the Council requires Member States to communicate to the Commission and to the other Member States any draft national technical regulation concerning any product, including agricultural and fishery products, and a statement of the grounds which make the enactment of that regulation 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 in individual cases to specific goods. This Regulation should lay down procedures for the application of the mutual recognition principle in individual cases by, for example, requiring Member States to indicate the national technical rules on which the administrative decision is based and the legitimate public interest ground justifying the application of that national technical rule with respect to a good lawfully marketed in another Member State. The proportionality of the national technical rule is the basis for demonstrating that the administrative decision, which is based on that rule, is proportionate. However, the means to demonstrate the proportionality of the administrative decision should be the result of a case by case evaluation.
- (24) As administrative decisions denying or restricting market access for goods already lawfully marketed in another Member State should be an exception to the fundamental principle of free movement of goods, it is necessary to ensure that such decisions observe the existing obligations deriving from the mutual recognition principle. For this purpose it is appropriate to establish a clear procedure to determine whether goods are lawfully marketed in that 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 of the Treaty and the case-law of the Court of Justice. Such procedure should ensure that administrative decisions taken are proportionate and respect the mutual recognition principle and this Regulation.
- (25) While a competent authority is assessing goods before deciding whether or not it should deny or restrict market access, it should not be able to take decisions suspending market access, except where rapid intervention is required to prevent harm to safety or health of persons or to the environment, or to prevent the goods being made available 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.

- (26) Regulation (EC) No 765/2008 of the European Parliament and of the Council<sup>3</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 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 test reports and certificates issued by other conformity assessment bodies in accordance with Union law. Competent authorities should be required to take due account of the content of the test reports or certificates presented.
- (27) Directive 2001/95/EC of the European Parliament and of the Council<sup>4</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 authorities to ban any dangerous product with immediate effect or, for the period needed for the various safety evaluations, checks and controls, to ban temporarily a product that could be dangerous. It also describes the procedure for authorities to apply appropriate measures such as those referred to in Article 8(1)(b) to (f) thereof, in case of products posing a risk, and it also establishes the obligation to notify those measures to the Commission and other Member States. Therefore, competent authorities should be able to continue applying that Directive and in particular the provisions contained in Articles 8(1)(b) to (f) and Article 8(3) of that Directive.
- (28) Regulation (EC) No 178/2002 of the European Parliament and of the Council<sup>5</sup> establishes, inter alia, a rapid alert system for the notification of a direct or indirect risk to human health deriving from food or feed. It obliges Member States to notify the Commission immediately, under the rapid alert system of any measure they adopt which is aimed at restricting the placing on the market of, withdrawing or recalling food or feed in order to protect human health, and which requires rapid action. Competent authorities should be able to continue applying that Regulation and in particular the provisions contained in Articles 50(3) and 54 of that Regulation.

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<sup>3</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>4</sup> OJ L 11, 15.1.2002, p. 4.

<sup>5</sup> OJ L 31, 1.2.2002, p 1.

- (29) Regulation (EU) 2017/625 of European Parliament and of the Council establishes a harmonised Union framework for the organisation of official controls, and official activities other than official controls, along the entire agri-food chain, taking into account the rules on official controls laid down in Regulation (EC) No 882/2004 and in relevant sectoral legislation. It lays down a specific procedure to ensure that economic operators remedy a situation of non-compliance with feed and food law, animal health and animal welfare rules. Competent authorities should be able to continue applying that Regulation and in particular the provisions contained in Article 138 of that Regulation.
- (29a) Regulation (EU) No 1306/2013 of the European Parliament and of the Council establishes a harmonised Union framework for carrying out the checks in respect of the obligations laid down in Section II of Chapter I of Title II of Part 2 of Regulation (EU) No 1308/2013 in accordance with the criteria laid down in Article 4 of Regulation (EC) No 882/2004 of the European Parliament and of the Council and 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 that Regulation and in particular the provisions contained in Article 90 of that Regulation.
- (30) Any administrative decision taken by competent authorities of Member States pursuant to this Regulation should specify the remedies available so that an economic operator can, according to the national legislation, appeal the decision or bring proceedings before the competent national court or tribunal. The administrative decision should also refer to the possibility of economic operators to use the SOLVIT network and to have access to the problem-solving procedure provided for in this Regulation.
- (31) Effective solutions for economic operators wishing for a business friendly alternative when challenging administrative decisions denying or restricting market access are essential to ensure a correct and consistent application of the mutual recognition principle. In order to guarantee such solutions, and to avoid legal costs, especially for SMEs, a non-judicial problem-solving procedure should be available for economic operators.
- (32) The Internal Market Problem Solving Network (SOLVIT) is a service provided by the national administration in each Member State aiming to find solutions for citizens and businesses when their rights are breached by public authorities in another Member State. The principles governing the functioning of SOLVIT are set out in the Commission Recommendation 2013/461/EU, according to which each Member State should provide for a SOLVIT centre with adequate human and financial resources to ensure that the SOLVIT centre takes part in the European SOLVIT network. The Commission should increase awareness about the existence and benefits of SOLVIT, especially amongst businesses.

- (33) The SOLVIT system is an effective non-judicial, problem-solving mechanism that is provided free of charge. It works under short deadlines and provides practical solutions to citizens and businesses when they are experiencing difficulties with their Union rights being recognised by public authorities. Where the economic operator, the relevant SOLVIT centre and the involved Member States in question all agree on the appropriate outcome, no further action should be required.
- (34) However, where the SOLVIT's informal approach fails, and doubts remain regarding the compatibility of the administrative decision with the mutual recognition principle the Commission should be empowered to look into the matter at the request of any of the SOLVIT centres involved. Following an 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 and to be considered during the SOLVIT procedure. The Commission's intervention should be subject to a time-limit of 45 working days that would not include the time necessary for receiving the additional information and documents that might be deemed necessary. If the case is solved during this period, the Commission would not be required to issue an opinion. These SOLVIT cases should be subject to a separate workflow in the SOLVIT database and should not be included in the regular SOLVIT statistics.
- (34a) *deleted*
- (35) The opinion of the Commission as regards an administrative decision denying or restricting market access should only cover the questions of whether the administrative decision is compatible with the mutual recognition principle and whether it complies with the requirements of this Regulation. This is without prejudice to the Commission's powers under article 258 of the Treaty and the Member States' obligation to comply with the provisions of Union law, where systemic problems identified as regards the application of the mutual recognition principle can be further addressed.
- (36) It is important for the internal market in goods that businesses, and 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 how mutual recognition is applied in their territory. 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 rules covered by mutual recognition.

- (37) In order to facilitate the free movement of goods, Product Contact Points should be required to provide, up to a reasonable level, information, free of charge, 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 [Single Digital Gateway – COM(2017)256] they should provide information through a website and 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 an electronic copy of or online access to the national technical rule, should be performed without prejudice to the national rules governing their distribution. Furthermore, Product Contact Points should not be required to provide copies of or online access to standards which are subject to intellectual property rights of standardisation bodies and organisations.
- (38) Cooperation between competent authorities is essential for the smooth functioning of the mutual recognition principle and for creating a mutual recognition culture. Product Contact Points and national competent authorities should therefore be required to cooperate and exchange information and expertise in order to ensure a correct and consistent application of the principle and of this Regulation.
- (39) For the purposes of notifying administrative decisions denying or restricting market access, of allowing communication between Product Contact Points and of ensuring administrative cooperation, it is necessary to provide Member States with access to an information and communication system.
- (40) 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.
- (41) Where for the purposes of this Regulation it is necessary to process personal data, this 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 and Regulation (EC) No 45/2001 of the European Parliament and of the Council, as the case may be.
- (42) Reliable and efficient monitoring mechanisms should be established to provide information on the application of the Regulation and on its impact on the free movement of goods. Such mechanisms should not go beyond what is necessary to achieve these objectives.

- (43) For the purposes of raising awareness about the mutual recognition principle 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.
- (44) In order to remedy the lack of accurate data related to the functioning of the mutual recognition principle and its impacts on the Single Market for goods, Union should finance collection of such data.
- (45) 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.
- (46) *deleted*
- (47) 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 in it.
- (48) The Commission should carry out an evaluation of this Regulation against the objectives it pursues. The Commission should use the data collected on the functioning of the mutual recognition principle and its impacts on the single market for goods as well as 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 the evaluation. Pursuant to point 22 of the Interinstitutional Agreement of 13 April 2016 on Better Law Making, the evaluation, based on efficiency, effectiveness, relevance, coherence and value added, should provide the basis for impact assessments of options for further action.
- (49) Since the objectives of this Regulation, namely to ensure a smooth, consistent and correct application of the mutual recognition principle, cannot be sufficiently achieved by the Member States and can, therefore, by reason of their scale and effect, 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 the 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 mutual recognition principle and by removing unjustified barriers to trade.
1. 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 subject to Article 34 of the Treaty, which are lawfully marketed in another Member State, having regard to Article 36 of the Treaty and the case-law of the Court of Justice.

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) of the Treaty, and to administrative decisions taken or to be taken by a competent authority of a Member State ('the Member State of destination') in relation to any such goods lawfully marketed in another Member State, where the administrative decision meets both of the following criteria:
  - (a) the basis for the administrative decision is a national technical rule applicable in the Member State of destination;
  - (b) the direct or indirect effect of the administrative decision is to deny or restrict market access in the Member State of destination.
2. The reference in paragraph 1 to 'administrative decisions' includes any administrative step that is based on a national technical rule and has the same or substantially the same legal effect as that referred to in point (b) of paragraph 1.

3. 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 elements:
  - (a) the provision covers goods or aspects of goods that are not the subject of harmonisation at Union level;
  - (b) the provision either prohibits the making available of goods, or a type of goods, on the market in that Member State or else it makes compliance with the provision compulsory, de facto or de jure, whenever goods, or goods of a given type, are being made available on that market;
  - (c) the provision does at least one of the following:
    - (i) it lays down the characteristics required of those goods, or goods of that type, such as their levels of quality, performance or safety, or dimensions, including the requirements applicable to the goods or type of goods as regards the name under which they are sold, terminology, symbols, testing and test methods, packaging, marking or labelling and conformity assessment procedures;
    - (ii) it imposes on those goods, or goods of that type, other requirements that are imposed for the purposes of protecting consumers or the environment and 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 the goods, or type of goods, or the making available of them on the market in that Member State.
4. Paragraph 3(c)(i) also covers production methods and processes used in respect of agricultural products, as referred to in the second subparagraph of Article 38(1) of the Treaty, or products intended for human and animal consumption, as well as production methods and processes relating to other products, where these have an effect on their characteristics.
- 4a. This Regulation does not affect the obligation to notify draft national technical regulations to the Commission and the Member States prior to their adoption pursuant to Directive (EU) 2015/1535.
- 4b. *deleted*
5. A prior authorisation 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 a decision to which this Regulation applies if it fulfils the other requirements of paragraph 1.

6. 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.
7. Articles 5 and 6 shall not affect the application of the following provisions:
  - (a) Article 8(1)(b) to (f) and Article 8(3) of Directive 2001/95/EC;
  - (b) Article 50(3)(a) and Article 54 of Regulation (EC) No 178/2002;
  - (c) Article 138 of Regulation (EU) 2017/625;
  - (ca) Article 90 of Regulation (EU) 1306/2013.

### Article 3

#### Definitions

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

- (1) 'lawfully marketed in another Member State' means that the goods or type of goods comply with the relevant rules applicable in that Member State or are not subject to any rules in that Member State, and are made available to end users in that Member State;
- (2) 'making available on the market in a Member State' means any supply of the goods for distribution, consumption or use on the market within the territory of that 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 the goods can be made available on the market in the relevant Member State, or conditions for keeping the goods on that market, which in either case require the modification of one or more of the characteristics of those goods, as described in Article 2(3)(c)(i), or the performance of additional testing;

- (4) 'denying market access' means any of the following:
  - (a) prohibiting the goods from being made available on the market in the relevant Member State or from being kept on that market;
  - (b) requiring the withdrawal or recall of the goods from that market;
- (4a) 'withdrawal' means any measure aimed at preventing goods in the supply chain from being made available on the market;
- (4b) 'recall' means any measure aimed at achieving the return of goods that have already been made available to the end-user;
- (5) 'prior authorisation' 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;
- (6) 'producer' means:
  - (a) any natural or legal person who manufactures the goods or has the goods designed or manufactured, or who produces goods which were not obtained by a manufacturing process, including agricultural products, and markets them under his name or trademark, or
  - (b) any natural or legal person who modifies goods already lawfully marketed in a Member State in such a way that compliance with the relevant rules applicable in that Member State may be affected, or
  - (c) any other natural or legal person who, by putting his name, trademark or other distinguishing feature on the goods or on the accompanying documents presents himself as its producer;
- (7) 'authorised representative' means any natural or legal person established within the Union who has received a written mandate from the producer to act on the producer's behalf with regard to the making available of the goods on the market in question;
- (8) 'importer' means any natural or legal person established within the Union who makes the goods from a third country available on the Union market for the first time;

- (9) 'distributor' means any natural or legal person in the supply chain, other than the producer or the importer, who makes the goods available on the market in the relevant Member State;
- (10) 'economic operator' means any of the following in relation to the goods: the producer, the authorised representative, the importer or the distributor;
- (11) 'end user' means any natural or legal person, residing or established in the Union, to whom the goods have been or are being made available either as a consumer, outside any trade, business, craft or profession, or as a professional end user in the course of his industrial or professional activities;
- (12) 'legitimate public interest ground' means any of the grounds set out in Article 36 of the Treaty or any other overriding reasons of public interest;
- (12a) 'conformity assessment body' means conformity assessment body as defined in point 13 of Article 2 of Regulation (EC) 765/2008.
- (12b) *deleted*

## Chapter II

### Procedures concerning application of the mutual recognition principle in individual cases

#### Article 4

##### Mutual recognition declaration

1. The producer of goods, or goods of a given type, that are being or are to be made available on the market in the Member State of destination may draw up a voluntary declaration of lawful marketing for the purposes of mutual recognition (hereinafter referred to as 'mutual recognition declaration') in order to demonstrate to the competent authorities of the Member State of destination for the purpose of the assessment of goods pursuant to Article 5, that the goods, or goods of that type, are lawfully marketed in another Member State.

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

The producer may mandate his authorised representative to draw up the declaration on his behalf.

The producer or his mandated authorised representative may fill in the mutual recognition declaration only with the information set out in Part I of the Annex. In this case the specific information related to the marketing of the goods or that type of goods 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 and/or by the distributor, provided that the relevant signatory can supply the evidence referred to in point (a) of Article 5(1c).

2. *moved to paragraph 1*

The declaration shall be drawn up in one of the official languages of the Union and, where that language is not the language required by the Member State of destination, it shall be translated by the economic operators into a language required by the Member State of destination.

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

4. Economic operators shall ensure that the declaration is kept up to date at all times to reflect any changes in the information provided by them in the declaration.
5. 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.
6. Where economic operators make the declaration available online, the following conditions shall be satisfied:
  - (a) the goods type or series to which the declaration applies are easily identifiable;
  - (b) the technical means used ensure easy navigation and are monitored to ensure the availability of and access to the declaration.
7. *moved to Art. 5*
8. *moved to Art. 5*
9. 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 the goods subject to this Regulation, it shall contact the relevant economic operator without delay.
- 1a. The purpose of the assessment is to establish whether the goods or that type of goods 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.

When entering into contact with the relevant economic operator, the competent authority of the Member State of destination shall inform the economic operator about the assessment, indicating the goods that are subject to that assessment and of the applicable national technical rule or prior authorisation procedure. It shall also inform the economic operator of the possibility to supply a mutual recognition declaration in accordance with the requirements of Article 4 for the purpose of the abovementioned assessment.

- 1b. The economic operator shall be allowed to make the goods available on the market of the Member State of destination while the competent authority carries out the assessment under paragraph 1 and may continue to do so unless an administrative decision to restrict or deny market access for those goods is received. This provision shall not apply where the assessment is carried out in the framework of a prior authorisation procedure, or where the competent authority temporarily suspend the making available of these goods on the market in accordance with Article 6.
- 1c. If a mutual recognition declaration is supplied to a competent authority of the Member State of destination in accordance with the requirements of Article 4, then for the purposes of any assessment of the goods under paragraph 1:
  - (a) the declaration together with supporting evidence necessary to verify the information contained in it, 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
  - (b) 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.
- 1d. If a mutual recognition declaration is not supplied to a competent authority of the Member State of destination in accordance with the requirements of Article 4, for the purposes of the assessment under paragraph 1 the competent authority may request the relevant economic operators to provide the following relevant documentation and information, that is necessary for the assessment, concerning:
  - (a) the characteristics of the goods or type of goods in question;
  - (b) lawful marketing of the goods in another Member State;
- 1e. 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 under point (a) of paragraph 1c or 1d, or to submit any arguments or comments the economic operator may have.
- 1f. For the purpose of the assessment referred to above, the competent authority of the Member State of destination may, in accordance with Article 10(2), contact the competent authorities or the Product Contact Points of the Member State in which an economic operator claims to be lawfully marketing his goods, if the verification of any information provided by the economic operator is needed.

2. In carrying out assessments under paragraph 1, the competent authorities of Member States shall take due account of the content of test reports or certificates issued by a conformity assessment body and provided by any economic operator as part of the assessment. Competent authorities of Member States shall not refuse certificates or test reports 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.
3. Where, on completion of an assessment under paragraph 1, the competent authority of a Member State takes an administrative decision with respect to the goods, it shall communicate its decision without delay to the relevant economic operator referred to in paragraph 1. It shall also notify its decision to the Commission and to the other Member States no later than 20 working days after the decision has been taken by means of the system referred to in Article 11.
4. The administrative decision referred to in paragraph 3 shall set out the reasons for the decision in a manner that is sufficiently detailed and reasoned to facilitate an assessment to be made of its compatibility with the mutual recognition principle and with the requirements of this Regulation.
5. In particular, the following information shall be included in the administrative decision referred to in paragraph 3:
  - (a) the national technical rule on which the administrative decision is based;
  - (b) the legitimate public interest ground justifying the application of the national technical rule on which the administrative decision is based;
  - (c) the technical or scientific evidence considered, including, where applicable, any relevant changes in the state of the art that have occurred since the national technical rule came into force;
  - (d) a summary of the arguments relevant for the assessment put forward by the relevant economic operator, if such were provided;
  - (e) the evidence demonstrating that the administrative decision is appropriate for the purpose of achieving the objective pursued and that it does not go beyond what is necessary in order to attain that objective.

6. The administrative decision referred to in paragraph 3 shall specify the remedies available under the law in force in the Member State concerned and the time limits applicable to those remedies, and it shall also include a reference to the possibility of economic operators to use the SOLVIT network and to have access to the procedure under Article 8.
7. The administrative decision referred to in paragraph 3 shall not take effect before it has been notified to the relevant economic operator under that paragraph.

## Article 6

### Temporary suspension of market access

1. While 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 in one or the other of the following situations:
  - (a) under normal or reasonably foreseeable conditions of use, the goods posing 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;
  - (b) the making available of the goods, or 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 relevant economic operator, the Commission and the other Member States of any temporary suspension pursuant to paragraph 1. The notification to the Commission and 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 is considered to fall within that point.

## Article 7

### Notification under the Rapid Information Exchange System (RAPEX) or Rapid Alert System for Food and Feed (RASFF)

1. If the administrative decision referred to in Article 5 or the temporary suspension referred to in Article 6 is also a measure which is required to be notified through RAPEX as referred to in Directive 2001/95/EC or through the RASFF as referred to in Regulation (EC) No 178/2002, a separate notification to the Commission and the other Member States under this Regulation is not required, provided that the following conditions are met:
  - (a) the RAPEX or RASFF notification indicates that notification of the measure also counts as notification under this Regulation;
  - (b) the supporting evidence required for the administrative decision under Article 5 or for the temporary suspension under Article 6 is enclosed with the RAPEX or RASFF notification.

## Article 8

### Problem-solving procedure

1. This Article applies if an economic operator affected by an administrative decision has submitted the decision to the Internal Market Problem Solving Network (SOLVIT) and, during the SOLVIT procedure, the Home Centre or the Lead Centre asks the Commission to give an opinion to assist in solving the case. SOLVIT Home and Lead Centres shall provide the Commission with all relevant documents relative to the decision at stake.
2. After receiving the request referred to in paragraph 1, the Commission shall, without undue delay, assess the compatibility of the administrative decision with the principle of mutual recognition and this Regulation.
- 2a. For the purposes of the assessment referred to in paragraph 2, the Commission shall consider the administrative decision notified in accordance with Article 5(3) 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, 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 who took the administrative decision in order to provide such additional information or documents.

3. 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 days period does not include the time necessary for receiving the additional information and documents as provided for in paragraph 2a.
- 3a. Where the Commission is informed that the case is solved during the assessment referred to in paragraph 2, the Commission is not required to issue an opinion.
4. The Commission's opinion shall be communicated through the relevant SOLVIT Centre to the economic operator concerned and to the relevant competent authorities. It 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.
- 4a. *deleted*
- 4b. *deleted*

## 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 ensure that their Product Contact Points have sufficient powers and are adequately resourced for the proper performance of their tasks. They shall ensure that Product Contact Points deliver their services in accordance with Regulation (Single Digital Gateway – COM(2017)256).
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 that Member State, including information on the procedure set out in Article 5;
  - (b) the contact details of the competent authorities within that Member State by means of which they 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 that Member State;
  - (c) the remedies and procedures available in the territory of that Member State in the event of a dispute between the competent authority and an economic operator, including the procedure described in Article 8.
- 2a. *deleted*
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 an electronic copy of or an online access to the national technical rules and national administrative procedures applicable to specific goods or a specific type of goods in the territory in which the Product Contact Point is established and information as whether the 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 between the competent authorities and the Product Contact Points of the various Member States, by the following means:
  - (a) facilitating and coordinating the exchange and collection of information and best practices with regard to the application of mutual recognition principle;
  - (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. Upon request by competent authorities of the Member State pursuant to Article 5 paragraph 1f, competent authorities in the Member State in which an economic operator claims to be lawfully marketing his goods shall provide the competent authorities of that other Member State 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 facilitate the contacts between the relevant competent authorities in accordance with time limits for providing the requested information set out in Article 9(4).
- 2a. *deleted*
3. Member States shall ensure that their competent authorities and Product Contact Points participate in the activities referred to in paragraph 1.

## Article 11

### Information and communication system

1. For the purposes of Articles 5, 6 and 10, the Union information and communication system set out in [Article 34 of Regulation on compliance and enforcement/Article 23 of Regulation (EC) No 765/2008] shall be used, except as provided in Article 7.
2. The Commission shall adopt implementing acts specifying the details of the system referred to in paragraph 1 and its functionalities 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 good practices;
  - (d) the functioning of cooperation amongst Product Contact Points and competent authorities, and the technical and logistic support for this cooperation;
  - (e) collection of data related to the functioning of the mutual recognition principle and its impacts on the Single Market for goods.
2. The Union's financial assistance with respect to activities under this Regulation shall be implemented in accordance with Regulation (EU, Euratom) No 966/2012 of the European Parliament and the Council, either directly or by delegating budget implementation tasks to the entities listed in Article 58(1)(c) 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 procedures laid down in Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council and Council Regulation (Euratom, EC) No 2185/96 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.

## Chapter V

### Review and Committee procedure

#### Article 14

##### Evaluation

1. By ... [Publications office, please insert the date five years after the date of application], and every four years thereafter, the Commission shall carry out an evaluation of this Regulation against the objectives 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, the Commission shall use the information available in the system referred to in Article 11 and the data collected as referred to in Article 12(1)(e). 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 and of 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 ... [Publications office, please insert the date 1 year after the date of entry into force]. 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 ... [Publications office, please insert the date 1 year after the date of entry into force].

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

Done at Brussels,

*For the European Parliament*

*The President*

*For the Council*

*The President*

Mutual recognition declaration for the purposes of Article 4 of Regulation [XXX/YYYY - add full title in a footnote]

### **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]
  - 1a. *deleted*
2. Name and address of the economic operator: [Note: insert the name and address of the signatory of Part I of the declaration: the producer and, where applicable, his authorised representative, or the importer, or the distributor]
3. Description of the goods or type of goods subject of the 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 administrative decision if the goods were subject to a prior authorisation], or the goods or type of goods described above are not subject to any 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, and/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):

4a 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.:

4b This part of the declaration is issued under the sole responsibility of the economic operator identified under point 2.

Signed for and on behalf of:

(place and date of issue):

(name, function) (signature):

**Part II**

5. Declaration and information on the marketing of the goods or that type of goods:
  - 5.1. The goods or that type of goods are made available to end users on the market in the Member State indicated in point 4.1.
  - 5.2. 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:
6. 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:
7. This part of the declaration is issued under the sole responsibility of [Note: insert the name and address of the signatory of Part II of the declaration: the producer and, where applicable, his authorised representative, or the importer, or the distributor].

Signed for and on behalf of

(place and date of issue):

(name, function) (signature):

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