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**NOTE**

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From: Presidency  
To: Council

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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 (first reading)  
- General approach

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**I. INTRODUCTION**

1. On 19 December 2017, the Commission transmitted the above-mentioned proposal for a Regulation to the European Parliament and to the Council. It is a part of the so-called "Goods package", which also contains the proposal for a Regulation laying down rules and procedures for compliance with and enforcement of Union harmonisation legislation on products.

2. The objective of this Regulation is to improve the application of the principle of mutual recognition, and thus to ensure that goods lawfully marketed in one Member State can be sold in any other Member State, as long as they are safe and respect the public interest. The current legislative framework does not ensure a reliable application of this principle as market access of goods, which are considered safe and in line with the public interest in one Member State, may be denied or restricted in another Member State. Consequently, businesses (in particular SMEs) are facing unwarranted costs and delays, because they have to adapt their goods to the requirements of (several) national markets.
3. As far as consistency of the proposed Regulation with the existing legislation in the area of free movement of goods in the internal market is concerned, the proposed Regulation is fully complementary to the EU harmonisation legislation. It aims at promoting the principle of mutual recognition and it applies to both goods that are not subject to the EU harmonisation legislation and goods that are only partly covered by it. The EU harmonisation legislation sets out common requirements on how products have to be manufactured. Where there are no EU common rules or when goods are only partially covered by EU common rules, Member States remain free to adopt their national technical rules laying down requirements to be met by those goods (in terms of designation, form, size, labelling, packaging, etc.). The proposed Regulation thus ensures that Member States do so in full respect of the principle of mutual recognition.
4. In comparison with the current legislative framework (namely, the Regulation (EC) 764/2008) several changes have been introduced in the proposed Regulation, so as to strengthen functioning of the internal market by improving the application of the principle of mutual recognition:
  - clarifying the scope of mutual recognition, in particularly when this principle is applicable. This will increase legal certainty for businesses and national authorities as to when the principle of mutual recognition can be applied;

- introducing a self-declaration to facilitate demonstrating that goods have already been lawfully marketed in a Member State. This is meant to enable economic operators to benefit from the use of such a declaration within the framework of assessment of goods in question;
  - establishing a problem-solving procedure to provide practical solutions to citizens and businesses in terms of compatibility of an administrative decision denying or restricting market access with the principle of mutual recognition. The use of this non-judicial mechanism will make the application of the principle by businesses and national authorities easier;
  - setting up efficient administrative cooperation to enhance exchange of information and trust among competent authorities of the Member States, and thus to facilitate the application of the principle of mutual recognition.
5. The main responsible committee in the European Parliament is the Committee on the Internal Market and Consumer Protection (IMCO). Mr Ivan ŠTEFANEC (EPP – SK) has been appointed as a rapporteur. The IMCO draft report has already been finalised, and it was discussed on 16-17 May 2018.

## **II. WORK CONDUCTED WITHIN THE COUNCIL**

6. The first meeting of the Working Party on Technical Harmonisation (Goods package) was held on 23 January 2018. During the meeting, the Commission presented both proposals included in the Goods Package – the Mutual Recognition Regulation and the Compliance and Enforcement Regulation.

7. The impact assessment accompanying the proposal was also examined on 23 January 2018. It focused on certain aspects, for which delegations requested further clarifications. In general, both the impact assessment and the proposal received a positive response from delegations.
8. There is a general support of Member States for the overall objective of the proposal, i.e. to strengthen the functioning of the internal market by improving the application of the principle of mutual recognition. All Member States acknowledge the need to modify the current legislative framework in order to reduce differences in the interpretation and application of the principle of mutual recognition by national authorities and to remove obstacles hampering a truly level playing field for businesses.
9. The examination of the proposal itself by the Working Party on Technical Harmonisation (Goods package) started in February 2018. Following the first, rather general meeting on 23 January 2018, four other meetings of the Working Party have been held under the Bulgarian Presidency, which focused on detailed examination of the proposal. Extensive discussions during the meetings, as well as written comments submitted by a large number of Member States resulted in three consecutive revised versions of the proposal presented to the delegations as Presidency discussion papers.
10. At the Working Party level, the text of the revised versions has been examined with a view to clarify and streamline the framework of mutual recognition. In the course of discussions, the proposal has evolved considerably with a view to achieving better clarity and accommodating concerns raised by the Member States, thus ensuring the right balance between the delegations positions.
11. Following the Working Party meeting on 2 May 2018, the Presidency prepared a compromise proposal as set out in document 8674/18, with a view to agree on a general approach at the forthcoming Competitiveness Council to be held on 28 May 2018.

12. The Presidency compromise text as set out in document 8674/18 was discussed at the Permanent Representatives Committee (COREPER) on 16 May 2018 and slightly modified. A qualified majority of delegations can accept the revised Presidency compromise. At the end of the discussions, the Chair concluded that the revised compromise will be submitted to the Competitiveness Council on 28 May 2018, with a view to reaching a general approach.

The revised Presidency compromise text as it stands following the COREPER on 16 May 2018, is set out in document 8706/18.

### III. MAIN ISSUES

13. The Presidency has identified the following articles as main issues:

- Article 1 (Subject matter)
- Article 4 (Mutual recognition declaration)
- Article 5 (Assessment of goods)
- Article 8 (Problem-solving procedure)

a) Subject matter (Article 1)

In the course of discussions, particularly during the last Working Party meeting on 2 May 2018, some doubts were raised by delegations as to whether the reference made in Article 1 to Article 36 of the Treaty guarantees that Member States will be able to further protect the legitimate public interests covered by their national technical rules. Taking account of views expressed by different delegations, a compromise wording has been suggested in order to make clear that the reference to “Union law” in the current wording of Article 1 means that a due account is taken both of Article 36 and the case law of the Court of Justice.

b) Mutual recognition declaration (Article 4 together with the Annex and Recitals 15 – 21)

Two substantial issues concerning the declaration have been raised by delegations: who may draw up the declaration and who is responsible for the information provided in the declaration. Certain doubts have been expressed as regards limiting the possibility of drawing up the declaration only by the producer and by his authorised representative on the basis of a mandate received, and providing specific information related to marketing of goods only by other economic operators, such as distributors and importers.

In the course of discussions, it was found reasonable to separate the declaration in two parts and to expand the possibility of drawing up the declaration to all economic operators. Thus the responsibility for the content and accuracy of information in each part is taken by economic operators signing the relevant part.

The latest Presidency compromise strikes the right balance between providing more opportunities for economic operators to draw up mutual recognition declaration, and at the same time ensuring that the relevant economic operators take the necessary responsibility.

c) Assessment of goods (Article 5 and Recitals 22, 23, 24, 26 and 30)

Due to the extensive debates on Article 5 as a core of the proposal, certain changes have been introduced with a view to clarifying the purpose and procedural steps for carrying out assessment of goods. In addition, the right of providing information by economic operators for the purposes of assessment, as well as sufficient time limit for reaction have been ensured. The assessment procedure under Article 5 was linked with the administrative cooperation mechanism under Article 10.

Article 5 and the corresponding Recital 24 were amended following the COREPER discussions on 16 May, together with Article 10.

d) Problem-solving procedure (Article 8 and Recitals 30-35)

Generally, the informal character of the SOLVIT procedure has been kept. The Commission's involvement in the procedure, by a non-legally binding opinion, is explicitly clarified.

The following aspects have been further clarified:

- procedural steps to be taken;
- timing for the Commission's involvement. The opinion has to be issued within a specified time limit;
- accessibility of the Commission's opinion. The opinion has to be communicated to the concerned economic operators and to the relevant competent authorities (by the relevant SOLVIT centre), as well as to all Member States (through the system referred to in Article 11).

#### IV. CONCLUSION

14. The Presidency compromise text reflects efforts of the Presidency and Member States to strike the right balance between different interests on the above issues.

On this basis, the Council is invited to agree on a general approach at the Competitiveness Council on 28 May 2018.

Marking of changes (except titles of chapters and of articles):

With respect to the document 8674/18, new additions appear in **bold/underlined** and new deletions in comparison to the Commission proposal are in ~~strikethrough~~. Text, which was deleted from the document 8674/18, is in **bold**.

With respect to the Commission proposal, previous additions are in **bold** and previous deletions are in ~~strikethrough~~.

2017/0354 (COD)

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:

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



- (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.
- (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, ~~or manufactured~~ **including 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, and which in either case are proportionate to the aim pursued.
- (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. This concept covers, inter alia, the effectiveness of fiscal supervision, the fairness of commercial transactions, protection of consumers, protection of the environment, the maintenance of press diversity and the risk of seriously undermining the financial balance of the social security system. Such overriding reasons, where legitimate differences exist from one Member State to another, may justify the application of national rules by the competent authorities. However, ~~such~~ **administrative** decisions need to be duly justified, and the principle of proportionality must always be respected, regard being had to whether the competent authority has in fact made the least restrictive decision possible. 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 domestic goods in that Member State fulfil that objective.

- (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.

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

- (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 ~~to~~ **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 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.
- (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.
- (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.
- (12) It is important to clarify that the term 'producer' includes not only the manufacturer of goods, but also the ~~person who presents himself as the producer of goods, such as~~ agricultural products, which were not obtained by a manufacturing process.
- (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 ~~being~~ made available to end users in that Member State.
- (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 be able to 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 declaration does not prevent national authorities from taking an **administrative** decision restricting market access, on the condition that such a decision is proportionate and respects the mutual recognition principle and this Regulation.

- (16) ~~The producer, or the producer's representative, should be responsible for filling in the information in the mutual recognition declaration as the producer knows the goods best. However, the information that the goods are being made available to end users in the relevant Member State may be in the possession of an importer or a distributor, rather than the actual producer. It should therefore be permissible for another economic operator to fill in this information in place of the producer.~~ **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 should be able to mandate his authorised representative to draw up such declaration on his behalf and under his responsibility. As the producer knows the goods best and is in a possession of the evidence that his goods meet certain requirements, if an importer or a distributor draws up such a declaration, he should be able to supply the evidence necessary for verification of the information contained in the declaration. 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.**
- (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, ~~as necessary,~~ **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 ~~contained~~ **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**.
- (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 information provided in~~ the mutual recognition declaration under this Regulation to be ~~included as part of that~~ **attached to the** EU declaration of conformity.
- (22) Where ~~producers~~ **economic operators** decide not to make use of the mutual recognition declaration ~~mechanism~~, it should be for the **competent authorities of the** Member State to request ~~the~~ **specific and clearly defined** information that ~~it~~ **they** considers necessary for the assessment of the goods, taking due account 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 applicable national technical rule** on which the administrative decision is ~~justified~~ **based**. This requirement does not, however, oblige Member States to justify the national technical rule itself, but rather the application of that national technical rule with respect to a ~~product~~ **good** lawfully marketed in another Member State. **In most of the cases the proportionality of the national technical rule should be sufficient by itself to demonstrate 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 appropriate to establish a clear procedure designed to ensure that such decisions to determine whether such goods are lawfully marketed in that Member State and, if so, that Member States observe the existing obligations deriving from the mutual recognition principle. Such procedure **should** ensure that **administrative** decisions taken are proportionate and respect the mutual recognition principle and this Regulation. When observing those obligations, Member States should be able to ensure that their legitimate public interests are adequately protected, in accordance with Article 36 of the Treaty and the case law of the Court of Justice.
- (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 ~~and~~ **or** health of ~~users~~ **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 also accept 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.

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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).

- (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)(~~db~~) 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>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<sup>6</sup> 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.

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<sup>6</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).

- (29a) **Regulation (EU) No 1306/2013 of the European Parliament and of the Council<sup>7</sup> 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<sup>8</sup> in accordance with the criteria laid down in Article 4 of Regulation (EC) No 882/2004 of the European Parliament and of the Council<sup>9</sup> 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.

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<sup>7</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. 549–607).**

<sup>8</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. 671–854).**

<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).**

- (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<sup>10</sup>.

**[Recitals 33 and 34 are merged]**

- (33) The SOLVIT system has proved to be 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. ~~Therefore, economic operators should have to rely on SOLVIT first before the problem-solving mechanism under this Regulation can be triggered.~~ 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.

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

- (34) — However, where the SOLVIT's informal approach fails, and ~~serious doubts remain regarding~~ the compatibility of the administrative decision with the mutual recognition principle the Commission should be empowered to look into the matter ~~and provide an assessment to be taken into account by the competent national authorities~~ at the request of **the 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 reasonable time-limit, ~~in compliance with the European Code of Good Administrative Behaviour.~~ **These SOLVIT cases should be subject to a separate workflow in the SOLVIT database and should not be included in the regular SOLVIT statistics.**
- (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 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 required by that Regulation,~~ 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 an electronic link 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 electronic links 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 ~~support~~ 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<sup>11</sup>.
- (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<sup>12</sup> and Regulation (EC) No 45/2001 of the European Parliament and of the Council<sup>13</sup>, 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 the Union should finance financing of** awareness-raising campaigns and other related activities aiming at enhancing trust and cooperation between competent authorities and economic operators.

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<sup>11</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.

<sup>12</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>13</sup> Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

- (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.

**[Covered by recital (48)]**

- ~~(46) The Commission should carry out an evaluation of this Regulation. The evaluation should be based on the five criteria of effectiveness, efficiency, relevance, coherence and added value and should provide the basis for impact assessments of possible further measures.~~
- (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 support system to evaluate this Regulation. **The** Commission should be able to ~~ask~~ **request** Member States ~~request for~~ **to provide** additional information necessary for the evaluation. Pursuant to point 22 of the Interinstitutional Agreement of 13 April 2016 on Better Law Making<sup>14</sup>, 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:

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<sup>14</sup> OJ L 123, 12.5.2016, p. 1.

# 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.**
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 lawfully marketed in another Member State ~~and subject to Articles 34 and 36 of the Treaty.~~  
**It shall not affect the legitimate public interests that may be protected by national measures in accordance with Union law.**
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) 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 ~~a decision 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 ~~an area~~ **goods** or **aspects of goods** that ~~is~~ **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 ~~domestic~~ 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 ~~domestic~~ 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 ~~domestic~~ 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. Technical specifications drawn up for public procurement procedures and requirements to use an official language of the Member State of destination shall not constitute national technical rules within the meaning of this Regulation.**
5. A ~~requirement for~~ 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 ~~may~~ **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)(~~db~~) to (f) ~~or~~ **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 ~~domestic~~-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 ~~domestic~~ 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 ~~domestic~~-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 **mandatory or voluntary** 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~~s its formal approval before goods may be made available on the ~~domestic~~ 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**, 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 ~~domestic~~ 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 ~~established in the Union,~~ other than the producer or the importer, who makes the goods available on the ~~domestic~~ 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.

## 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 ~~domestic~~ market in a ~~Member State~~ ('the Member State of destination') may draw up a declaration **of lawful marketing for the purposes of mutual recognition (a-hereinafter referred to as 'mutual recognition declaration')** in order to demonstrate to the competent authorities of the Member State of destination that the goods, or goods of that type, are lawfully marketed in another Member State.

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

~~Within~~ **Where the mutual recognition declaration drawn up by the producer contains only the information set out in Part I of the Annex, in order the declaration to be considered during the assessment under Article 5 the specific information related to the marketing of the goods or that type of goods set out in Part II of the Annex may, however, shall be filled in by any economic operator the importer or by the distributor.**

**Alternatively, the mutual recognition declaration may be drawn up by an importer and/or a distributor provided that all the information required under the Annex is included in the declaration and that the relevant signatory can supply the evidence referred to in point (a) of Article 5(1a).**

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

The declaration shall be ~~completed~~ **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 ~~the a language or languages~~ **a language** required by the Member State of destination.

3. Economic operators shall be responsible for the content and accuracy of the information that they themselves provide in the mutual recognition declaration.
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 competent authority of the Member State of destination.**
6. **Where** economic operators ~~may~~ make the declaration available ~~on a website online,~~ **provided that** the following conditions ~~are~~ **shall be** satisfied:
  - (a) the goods type or series to which the declaration applies are easily identifiable ~~on the website;~~

- (b) ~~the website is~~ **technical means used ensure easy navigation and are** monitored to ensure the availability of and access to the declaration;
- (c) ~~there are instructions provided on how to navigate the website and access the declaration.~~

**[Moved to Article 5]**

~~7. If a mutual recognition declaration is supplied to a competent authority of the Member State of destination in accordance with the requirements of this Article, then for the purposes of any assessment of the goods under Article 5:~~

- (a) ~~the declaration, together with any evidence reasonably required by the competent authority to verify the information contained in it, 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.~~

~~8. If a mutual recognition declaration is not supplied to a competent authority of the Member State of destination in accordance with the requirements of this Article, the competent authority may request any of the economic operators to provide the following documentation and information in order to demonstrate for the purposes of an assessment under Article 5 that the goods are lawfully marketed in another Member State:~~

- (a) ~~any relevant information concerning the characteristics of the goods or type of goods in question;~~

(b) ~~any relevant information on the lawful marketing of the goods in another Member State;~~

(c) ~~any other information the competent authority considers useful for the purposes of its assessment.~~

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 ~~included as part of that~~ **attached to the** EU declaration of conformity.

*Article 5*  
***Assessment of goods***

1. Where, **in the framework of the implementation of a national technical rule or a prior authorisation procedure**, a competent authority of a **the Member State of destination** ~~has doubts as regards goods which the economic operator claims are lawfully marketed in another Member State~~ **intends to take an administrative decision in relation to goods which are subject to this Regulation**, the competent authority shall contact the relevant economic operator without delay and shall carry out an assessment **of** the goods.

**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 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 the competent authority enters into contact with the relevant economic operator, it shall inform the economic operator of the goods that are subject to that assessment and of the applicable national technical rule.**

**The competent authority of the Member State of destination shall also inform the economic operator of the possibility to supply a mutual recognition declaration in accordance with the requirements of Article 4.**

- 1aa. Except where the assessment under paragraph 1 is carried out in the framework of a prior authorisation procedure, 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 and may continue to do so unless an administrative decision to restrict or deny market access for those goods is received.**
- 1a. If a mutual recognition declaration is supplied to the 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 any evidence reasonably required by the competent authority to verify the information contained in it, 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.**
- 1b. If a mutual recognition declaration is not supplied to the 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 information as follows:**
- (a) on the characteristics of the goods or type of goods in question;**

**(b) on the lawful marketing of the goods in another Member State.**

- 1c. The economic operator concerned shall be allowed at least 20 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 1a or paragraph 1b, or to submit any arguments or comments the economic operator may have.**
- 1d. Where, after the economic operator has submitted the documents and information under point (a) of paragraph 1a or paragraph 1b, the competent authority of the Member State of destination still has doubts that the goods have been lawfully marketed in another Member State, it may request the competent authorities ~~or the Product Contact Points~~ of that Member State to provide any information relevant for verifying data and documents supplied by the economic operator, as referred to in Article 10.**
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~~ **notify** its decision ~~within 20 working days~~ to the relevant economic operator referred to in paragraph 1, to the Commission and to the other Member States, **without undue delay and no more than 20 working days after the decision has been taken.** Notification to the Commission and to the other Member States shall be done 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 enable 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 applicable national technical rule** on which the **administrative** decision is ~~justified~~ based;
  - (c) the technical or scientific evidence considered, including, **where applicable**, any **relevant changes in the state of the art** ~~technical or scientific developments~~ that have occurred since the national technical rule ~~was adopted~~ **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. **By way of derogation from Article 5(1aa)**, while the competent authority of a Member State is carrying out an assessment of goods pursuant to Article 5, it ~~shall not~~ **may** temporarily suspend the making available of those goods on the ~~domestic~~ market in that Member State, ~~except~~ **only** in one or the other of the following situations:
  - (a) under normal or reasonably foreseeable conditions of use, the goods pose **or could 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;
  - (b) the making available of the goods, or goods of that type, on the ~~domestic~~ 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 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)***

4. 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 ~~the General Product Safety 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.
  
2. **After receiving the request referred to in paragraph 1 the Commission shall, without undue delay,** ~~The Commission shall, within three months of receipt of the request referred to in paragraph 1, enter into communication with the relevant economic operator or operators and the competent authorities who took the administrative decision in order to~~ 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 obtained during the SOLVIT procedure. Where additional information or documents are necessary for completing the assessment referred to in paragraph 2, the Commission shall 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 six weeks of receipt of the request referred to in paragraph 1** ~~Following completion of its assessment, the Commission may~~ **shall** issue an opinion. **Where appropriate, the Commission's opinion shall** ~~identify any concerns that should, in its view, be addressed in the SOLVIT case and, where appropriate, making or shall make~~ recommendations to assist in solving the case. **The six weeks period does not include the time necessary for receiving the additional information and documents as provided for in paragraph 2a.**

**Where during the assessment referred to in paragraph 2, the Commission is informed that the case is solved, an opinion need not be given.**

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 considered during the SOLVIT procedure referred to in paragraph 1.
- 4a. **The problem solving procedure under this Article shall apply without prejudice to the relevant remedies procedures available under national law.**

## **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.

**Where, due to the complexity of organisation and distribution of functions among competent authorities in a Member State, not all of the required information under point (b) of the first subparagraph can be provided online the remaining information shall be provided upon request.**

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 electronic link to the national technical rules 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 ~~that~~ the goods or goods of that type are subject to ~~a requirement for~~ prior authorisation under national law.

**[Text moved to Recital 37]**

4. Product Contact Points shall respond within 15 working days of receiving any request under **the second subparagraph of paragraph 2 and under** paragraph 3.
5. Product Contact Points shall not charge any fee for the provision of the information under **the second subparagraph of paragraph 2 and under** paragraph 3.

*Article 10*  
***Administrative cooperation***

1. The Commission shall provide for and ensure efficient cooperation and exchange of information between the competent authorities and the Product Contact Points of the various Member States.
2. ~~Product Contact Points~~ **Competent authorities** in the Member State in which an economic operator claims to be lawfully marketing his goods shall provide the competent authorities of other Member States, upon request and within 15 working days, with any ~~relevant~~ information **relevant for verifying data and documents supplied during the assessment under Article 5** relating to those goods. **Without prejudice to the time limit for providing the requested information, the Product Contact Points may facilitate ~~direct~~ the contacts between the relevant competent authorities. ~~Direct contacts between the competent authorities of the relevant Member States shall be subject to the same time limit for providing the requested information.~~**
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 ~~support~~ system***

1. For the purposes of Articles 5, 6, and 10, the Union information and communication ~~support~~ 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;
  - (d) the functioning of cooperation amongst Product Contact Points 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<sup>15</sup>, 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.

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<sup>15</sup> Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

*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<sup>16</sup> and Council Regulation (Euratom, EC) No 2185/96<sup>17</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.

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<sup>16</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>17</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 L292, 14.11.1996, p.2.

## **Chapter V**

### **Review and Committee procedure**

#### *Article 14* **Evaluation**

1. By (...) [**Publications office, please insert the date 4 years after the date of entry into force**], and every five 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 ~~1 January 2020~~ ... **[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

For the Council

The President

The President

**Declaration of lawful marketing of goods for the purposes of mutual recognition declaration for  
the purposes of (Regulation [XXX/YYYY])**

**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 declaration: the producer or 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 comply with the ~~relevant~~ **following** rules applicable in [*Note: **identify** the Member State identified below 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** ~~of~~ 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 ~~domestic~~-market in a **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 ~~that~~ **the Member State indicated in point 4.1**, including details ~~of the relevant Member State~~ and of the date of when the goods were first made available to end users on the ~~domestic~~ 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 ~~that~~ **the** Member State **indicated in point 4.1:**
7. This **part of the** declaration is issued under the sole responsibility of ~~the signatories:~~ **[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):

*And if another economic operator fills in point 5:*

~~Signed for and on behalf of:~~

~~(place and date of issue)~~

~~(name, function) (signature)~~