COMMISSION NOTICE

Guidance document for the application of Regulation (EU) 2019/515 of the European Parliament and of the Council on the mutual recognition of goods lawfully marketed in another Member State

(Text with EEA relevance)

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1. INTRODUCTION

Regulation (EU) 2019/515 of the European Parliament and of the Council on the mutual recognition of goods lawfully marketed in another Member State ([1]) ('the Regulation') started to apply on 19 April 2020 and replaced Regulation (EC) No 764/2008 of the European Parliament and of the Council ([2]). The aim of the Regulation is to strengthen the functioning of the single market by improving the application of the principle of mutual recognition and by removing unjustified barriers to trade (Article 1(1) of the Regulation).

The purpose of this guidance document is to help businesses and national competent authorities to apply the Regulation ([3]). However, only the text of the Regulation itself has legal force. The interpretation of EU legislation is the exclusive competence of the Court of Justice of the European Union ('the Court').

The principle of mutual recognition stems from the case-law of the Court on Articles 34 and 36 of the Treaty on the Functioning of the European Union (TFEU). The Regulation lays down rules and procedures for the application of the principle of mutual recognition in individual cases (Article 1(2) of the Regulation).

Articles 34 and 36 TFEU apply in the absence of EU harmonisation rules covering goods or certain aspects of goods.

According to Article 34 TFEU, 'quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States'.

Article 36 TFEU states the following.

The provisions of Articles 34 and 35 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.

Restrictive measures may also be justified by other objectives identified by the case-law of the Court (the so-called mandatory requirements).

On the basis of Articles 34 and 36, the Court developed the principle of mutual recognition:

— Member States may not prohibit the sale on their territory of goods which are lawfully marketed in another Member State;

— Member States may restrict or deny the marketing of goods that have been lawfully marketed in another Member State, where such restriction or denial is justified on the grounds set out in Article 36 TFEU or on the basis of other reasons of public interest, recognised by the case-law of the Court.

2. SCOPE OF THE REGULATION (ARTICLE 2 OF THE REGULATION)

The Regulation applies to: 1) goods of any type that are lawfully marketed in another Member State; and 2) administrative decisions that have been taken or are to be taken by a competent authority of a Member State of destination in relation to any such goods. To fall under the scope of the Regulation, administrative decisions must be based on a national technical rule applicable in the Member State of destination, and must have as their direct or indirect effect the restriction or denial of market access in the Member State of destination (Article 2(1) of the Regulation).

Determining whether goods might benefit from the mutual recognition principle is not always straightforward. This is because Articles 34 and 36 TFEU – and therefore mutual recognition – apply to a very wide range of goods or aspects of goods not exhaustively covered by EU harmonisation legislation.

([1]) Regulation (EU) 2019/515 of the European Parliament and of the Council of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State and repealing Regulation (EC) No 764/2008 (OJ L 91, 29.3.2019, p. 1).

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

([3]) See the Commission Communication of 19 December 2017, *The Goods Package: Reinforcing trust in the single market* (COM(2017) 787 final), and recital 5 of the Regulation.

2.1. **Goods lawfully marketed in another Member State**

2.1.1. *Goods*

The Regulation applies to goods of any type, including agricultural products. The term ‘agricultural products’ includes products of fisheries, as provided for in Article 38(1) TFEU (Article 2(1) and recital 12 of the Regulation).

The Regulation concerns goods which are subject to Article 34 TFEU (Article 1(2) of the Regulation). According to Court case-law ‘only products which can be valued in money and which are capable, as such, of forming the subject of commercial transactions fall within the scope of the free movement of goods’ ([4]).

2.1.2. *Lawfully marketed in another Member State*

The Regulation concerns goods which are lawfully marketed in another Member State (Article 1(2) of the Regulation).

According to Article 3(1) of the Regulation, goods ‘lawfully marketed in another Member State’ are goods which ‘comply with the relevant rules applicable in that Member State or are not subject to any such rules in that Member State, and are made available to end users in that Member State’(Article 3(1) of the Regulation). That key definition encompasses two criteria, set out in the two bullet points below.

— **The first criterion** is that the goods or goods of that type must comply with the relevant rules applicable in the Member State of origin or must not be subject to any such rules in that Member State. Therefore, in the absence of relevant national technical rules related to the specific goods in the Member State of origin, the answer to the question of compliance of the goods with the national technical rules of that Member State is easier. When there are national technical rules in the Member State of origin, information about the characteristics of the goods and reference to the national law may in some cases be sufficient to show compliance. In other cases, a decision on prior authorisation could be necessary. It is necessary to bear in mind that Member States may follow very different systems for controlling goods before they are put on the market (prior authorisation procedures) or after they are put on the market (market surveillance). These different systems include situations where certain goods are not regulated at all and do not have to comply with national legal requirements. The fact that ‘compliance with the relevant rules’ for goods is conditioned by prior approval in one Member State does not necessarily mean that such approval would be required for the lawful marketing of the same goods in another Member State. The different requirements in Member States have no impact on the concept of lawful marketing.

— **The second criterion** of the concept of lawful marketing is that the goods were made available to end users in that Member State. Article 3(2) of the Regulation defines ‘making available on the market’ as ‘any supply of goods for distribution, consumption or use on the market within the territory of a Member State in the course of a commercial activity, whether in return for payment or free of charge’. Any document that contains: (i) unambiguous data to identify the goods or type of goods, and to identify suppliers, customers or end-users; and (ii) information on the date, such as an invoice, should be considered as necessary and sufficient evidence for the purpose of demonstrating that the criterion is fulfilled.

2.2. **‘Administrative decisions’ under the Regulation**

2.2.1. *What is an administrative decision?*

Article 2(1) of the Regulation specifies that the Regulation applies to ‘administrative decisions’ that have been taken or are to be taken by a competent authority of a Member State of destination in relation to any such goods that are lawfully marketed in another Member State, where the administrative decision meets the following **criteria**:

(a) the basis for the administrative decision is a national technical rule applicable in the Member State of destination; and

(b) the direct or indirect effect of the administrative decision is to restrict or deny market access in the Member State of destination.

([4]) Judgment of 14 April 2011, *Vlaamse Dierenartsenvereniging and Janssens*, Joined Cases C-42/10, C-45/10 and C-57/10, ECLI:EU:C:2011:253, paragraph 68 and case-law cited therein.

Article 2(1) of the Regulation further specifies that the term ‘administrative decision’ includes any administrative step that is based on a national technical rule and that has the same or substantially the same legal effect as the effect referred to in point (b).

This means that it is not necessary for the administrative step to bear the name ‘decision’. What is important is whether it concerns goods that are lawfully marketed in another Member State and satisfies both conditions (a) and (b) above.

2.2.2. *First criterion: national technical rules – basis for an administrative decision*

According to Article 2(2) of the Regulation, for the purposes of the Regulation, a ‘national technical rule’ is any provision of a law, regulation or other administrative provision of a Member State which has the following characteristics:

a) it covers goods or aspects of goods that are not the subject of harmonisation at EU level;

b) it either prohibits the making available of goods, or goods of a given type, on the market in that Member State, or it makes compliance with the provision compulsory, *de facto* or *de jure*, whenever goods, or goods of a given type, are made available on that market; and

c) it does at least one of the following:

— it lays down the characteristics required of goods or of goods of a given type, such as their levels of quality, performance or safety, or their dimensions, including the requirements applicable to those goods as regards the names under which they are sold, terminology, symbols, testing and test methods, packaging, marking or labelling and conformity assessment procedures ([5]);

— for the purpose of protecting consumers or the environment, it imposes other requirements on goods or goods of a given type that affect the life-cycle of the goods after they have been made available on the market in that Member State. These include conditions of use, recycling, reuse or disposal, where such conditions can significantly influence either the composition or nature of those goods, or the making available of them on the market in that Member State.

Article 2(2)(c) of the Regulation is inspired by Articles 1(1)(c) and 1(1)(d) of Directive (EU) 2015/1535 of the European Parliament and of the Council ([6]) (the ‘Transparency Directive’) and Article 1(2) and 1(3) of its predecessor, Directive 98/34/EC of the European Parliament and of the Council ([7]). Therefore, the jurisprudence on these provisions ([8]) could be useful reference points. It is important to note that national technical rules subject to the Transparency Directive that are not notified at draft stage are unenforceable against individuals ([9]). The notification procedure under the Transparency Directive is described in Chapter 4 of this guidance.

In addition, on the concept of *rules which significantly influence the making available of goods on the market*, we should mention that, according to the case-law of the Court, restrictions on the use of certain goods may be considered as obstacles to the free movement of goods, since they influence the behaviour of consumers. Consumers will not buy goods that they will not be able to use. The three bullet points below discuss some specific examples of this case-law.

([5]) This point also covers: (i) production methods and processes used in respect of agricultural products as referred to in the second subparagraph of Article 38(1) TFEU; (ii) the production methods and processes used in respect of products intended for human or animal consumption; and (iii) production methods and processes relating to other products, where these have an effect on their characteristics (see Article 2(3) of the Regulation).

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

([7]) Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services (OJ L 204, 21.7.1998, p. 37).

([8]) See, for instance, Judgment of 13 October 2016, *M. and S.*, C-303/15 ECLI:EU:C:2016:771; Judgment of 11 June 2015, *Berlington*, C-98/14, ECLI:EU:C:2015:386; Judgment of 19 July 2012, *Fortuna and Others*, Joined cases C-213/11, C-214/11 and C-217/11, ECLI:EU:C:2012:495; Judgment of 26 October 2006, *Commission v Hellenic Republic*, C-65/05 ECLI:EU:C:2006:673; Judgment of 8 November 2007, *Schwibbert*, C-20/05, ECLI:EU:C:2007:652; Judgment of 21 April 2005, *Lindberg*, C-267/03 ECLI:EU:C:2005:246; Judgment of 26 September 2018, *Van Gennip and Others*, C-137/17, ECLI:EU:C:2018:771.

([9]) Judgment of 30 April 1996, *CIA Security v Signalson*, C-194/94, ECLI:EU:C:1996:172.

— For instance, in its judgment in *Commission v Italy*, the Court held that a prohibition on the use of motorcycles towing trailers constitutes a measure having equivalent effect to quantitative restrictions on imports. This applies to the extent that the ban's effect is to hinder access to the market at issue for trailers specifically designed for motorcycles in as much as it has a considerable influence on the behaviour of consumers and prevents a demand from existing in the market at issue for such trailers ([10]). Consumers, knowing that they are not permitted to use their motorcycle with a trailer specially designed for it, have practically no interest in buying that trailer ([11]).

— Similarly, in *Mickelsson*, which concerned national regulations for the designation of navigable waters and waterways, the Court said that the restriction on the use of a product imposed by those regulations in the territory of a Member State could, depending on its scope, have a considerable influence on the behaviour of consumers. This may in turn affect the access of that product to the market of that Member State ([12]). Consumers, knowing that the use permitted by such regulations is very limited, have only a limited interest in buying that product ([13]). In that regard, the Court held that, where the national regulations for the designation of navigable waters and waterways have the effect of preventing users of personal watercraft from using them for the specific and inherent purposes for which they were intended or of greatly restricting their use, such regulations have the effect of hindering access to the domestic market in question for those goods and therefore constitute measures having equivalent effect to quantitative restrictions on imports ([14]).

— The Court also considered as contrary to Article 34 TFEU the ban on affixing tinted films to the windows of motor vehicles, stating, amongst others, that potential customers, traders or individuals have practically no interest in buying such films in the knowledge that affixing them to the windscreen and windows alongside passenger seats in motor vehicles is prohibited ([15]).

It is important to stress that the Regulation does not apply to administrative decisions based on other types of measures which are subject to Article 34 TFEU but do not constitute national technical rules, such as technical specifications drawn up for public procurement procedures or requirements to use official language(s) in the Member State in question (recital 10 of the Regulation).

In addition, rules on selling arrangements fall within the scope of Article 34 TFEU only under the condition that they introduce discrimination on the basis of the origin of products, either in law or in fact ([16]).

2.2.3. *Second criterion: the direct or indirect effect of the administrative decision is to restrict or deny market access in the Member State of destination*

As stated in Section 2.2.1, Article 2(1)(b) of the Regulation requires that 'the direct or indirect effect of the administrative decision is to restrict or deny market access in the Member State of destination'.

In *Dassonville* ([17]), the Court stated that 'all trading rules enacted by Member States which are capable of hindering, directly or indirectly, actually or potentially, intra-[EU] trade are to be considered as measures having an effect equivalent to quantitative restrictions'.

A good example of administrative decisions with the direct effect of restricting or denying market access could be those denying market access to jewellery lawfully marketed in another Member State on the grounds that they do not bear a hallmark or that the hallmark is not recognised in the Member State of destination. Mutual recognition often faces challenges in the area of precious metals.

([10]) Judgment of 10 February 2009, *Commission v Italy,* C-110/05, ECLI:EU:C:2009:66, paragraphs 56-58.
([11]) Judgment of 10 February 2009, *Commission v Italy,* C-110/05, ECLI:EU:C:2009:66, paragraph 57.
([12]) Judgment of 4 June 2009, *Mickelsson,* C-142/05, ECLI:EU:C:2009:336, paragraph 26.
([13]) Judgment of 4 June 2009, *Mickelsson,* C-142/05, ECLI:EU:C:2009:336, paragraph 27.
([14]) Judgment of 4 June 2009, *Mickelsson,* C-142/05, ECLI:EU:C:2009:336, paragraph 28.
([15]) Judgment of 10 April 2008, *Commission v Portuguese Republic,* C-265/06, ECLI:EU:C:2008:210, paragraph 33.
([16]) Judgment of 24 November 1993, *Keck and Mithouard,* Joined cases C-267/91 and C-268/91, ECLI:EU:C:1993:905, paragraphs 16 and 17. For more information about selling arrangements, see *Guide to the application of Treaty provisions governing the free movement of goods, 2010,* section 3.1.10.
([17]) Judgment of 11 July 1974, *Procureur du Roi v Benoît and Gustave Dassonville,* Case 8-74, ECLI:EU:C:1974:82.

Case C-525/14 *Commission v Czech Republic* concerned the Czech refusal to recognise the hallmarks of WaarborgHolland, an independent assay office established in the Netherlands with branches in third countries, and consequently the requirement for the precious metals in question to be marked with an additional Czech hallmark. The Court held that by virtue of that practice, precious metals marked with the WaarborgHolland hallmarks from a Netherlands assay office may be marketed in the territory of Czechia only after they have been the object of an additional control and hallmarking in Czechia. This additional control and hallmarking is liable to make the import of those products into the territory of Czechia from other Member States more difficult and costly. The practice is therefore considered prohibited by Article 34 TFEU in relation to hallmarks affixed in the Netherlands and not in third country branches.

Concerning the **indirect effect** of administrative decisions, it is important to bear in mind that it suffices that the administrative decision *could restrict or deny market access* in the Member State of destination. A decision has indirect effect if it is not in itself restricting or denying market access but is at least capable of doing so, according to factual circumstances and perceptions prevailing in the Member State ([18]).

Decisions which have only indirect effect on intra-EU trade should be clearly distinguished from decisions *whose effects are too indirect to have any effect*. The Court indeed considered, in certain cases ([19]), that the restrictive effects which a measure might have on the free movement of goods are *too uncertain and indirect* for the obligation which it lays down to be regarded as being of a nature to hinder trade between Member States and constitute a violation of Article 34 TFEU.

However, if a measure *covers only part of the national territory*, but has a direct or indirect effect on the free movement of goods, *it will be considered as a restriction* even if it is geographically limited.

For instance, in the *Ditlev Bluhme* ([20]) case, Danish legislation prohibited the keeping of bees on the island of Læsø other than those of the Læsø brown bee subspecies in order to protect the latter from extinction. Even though the measure was in force on this relatively small island in Denmark, the Court concluded that a prohibition on importation represents a measure having equivalent effect to a quantitative restriction and 'is not altered by the fact that the measure in question applies to only part of the national territory' ([21]). The Court rejected the argument that a prohibition of imports of goods (other types of bees) which is limited to part of the territory could be exempted on *de minimis* grounds as it only insignificantly affects the trade between Member States. However, the measure was found to be justified based on Article 36 of the Treaty on the grounds that the protection of the health and life of animals since the threat of the disappearance of the Læsø brown bees was undoubtedly genuine if they mated with golden bees due to the recessive nature of the genes of the brown bee.

2.2.4. *National technical rules and prior authorisation procedures*

National law sometimes requires prior authorisation before goods are placed on the market. A prior authorisation procedure means an administrative procedure under the law of a Member State requiring a competent authority of that Member State, 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 (Article 3(7) of the Regulation).

A prior authorisation procedure does not itself constitute a national technical rule for the purposes of the Regulation (Article 2(4) of the Regulation). Therefore, decisions of the competent authorities restricting or denying market access exclusively on the grounds that the goods do not have a valid prior authorisation are excluded from the scope of the Regulation (recital 11 of the Regulation).

However, a decision to refuse prior authorisation based on a national technical rule shall be considered to be an administrative decision to which the Regulation applies, if that decision fulfils the other requirements of the first subparagraph of Article 2(1) of the Regulation (Article 2(4) of the Regulation). This means that when the national rule that establishes the prior authorisation procedure gives effect to a national technical rule, any decision to refuse prior authorisation on the basis of a national technical rule constitutes an administrative decision under the Regulation. Hence, the applicant can benefit from the procedural protection that the Regulation provides (recital 11 of the Regulation).

([18]) Judgment of 8 September 2009, *Budějovický Budvar, národní podnik*, C-478/07, ECLI:EU:C:2009:521, paragraphs 81-82.
([19]) Judgment of 14 July 1994, *Peralta*, C-379/92, ECLI:EU:C:1994:296, paragraph 24.
([20]) Judgment of 3 December 1998, *Ditlev Bluhme*, C-67/97, ECLI:EU:C:1998:584, paragraphs 19-20.
([21]) *Ibidem*, paragraph 20.

2.2.5. *Some cases in which Regulation (EU) 2019/515 does not apply*

The Regulation does not apply to decisions of a judicial nature taken by national courts or tribunals (Article 2(5)(a) of the Regulation). That concerns decisions of national courts or tribunals assessing the legality of cases in which goods lawfully marketed in one Member State are not granted access to the market in another Member State (recital 14 of the Regulation).

Furthermore, the Regulation does not apply to 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 (Article 2(5)(b) of the Regulation).

3. HOW DOES MUTUAL RECOGNITION FUNCTION UNDER THE REGULATION?

3.1. **Lawful marketing of goods in the Member State of origin**

When marketing goods in another Member State in the absence of EU harmonisation legislation, economic operators should first make sure that the goods are compliant with the rules (or are not subject to any such rules) of the Member State of origin that apply on the day when these goods are placed on the market in the Member State of destination and are made available to end users in the Member State of origin. If the goods are lawfully marketed in the Member State of origin, then economic operators can refer to the mutual recognition principle before the competent authorities of the Member State of destination.

3.2. **Selling the goods in another Member State**

Article 5(3) of the Regulation says the following.

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

This means that once the conditions of Section 3.1 above are met, as a principle, the economic operator may make the goods available on the market in the Member State of destination. However, the economic operator should check if there is a prior authorisation procedure in the Member State of destination. If the marketing of the goods requires a prior authorisation in the Member State of destination, the economic operator must apply for this authorisation before the goods are made available on that market. The goods cannot be made available immediately on the market where a prior authorisation procedure applies, or where the competent authority decides to temporarily suspend the making available on the market of the goods that are subject to its assessment.

3.3. **Information about the assessment**

If a competent authority of the Member State of destination intends, as part of the implementation of a national technical rule, to assess goods that are subject to the Regulation, the economic operator must be informed without delay that such an assessment has been initiated (Article 5(1) of the Regulation). In particular, the competent authority must inform the economic operator of: (i) the goods subject to that assessment; (ii) the applicable national technical rule or prior authorisation procedure; and (iii) the possibility of supplying the competent authority with a mutual recognition declaration (Article 5(2) of the Regulation).

3.4. **The 'mutual recognition declaration' (Article 4 of the Regulation)**

The Regulation enables the producer, importer or distributor to draw up a voluntary declaration (or 'self-declaration') of the lawful marketing of the goods for the purposes of mutual recognition ('mutual recognition declaration'). This mutual recognition declaration helps businesses to demonstrate that the goods are lawfully marketed in another Member State. At the same time, it helps the competent authorities in the assessment procedure of goods under Article 5 of the Regulation and facilitates cross-border cooperation.

The competent authority of the Member State of destination must inform the economic operator if it intends to assess whether specific goods are lawfully marketed in another Member State (Article 5(1) of the Regulation). The Regulation ensures that the procedure is less burdensome for the economic operator when they opt for the declaration.

If a mutual recognition declaration is supplied to the competent authority of the Member State of destination, the competent authority shall not require any additional information and proof beyond those prescribed by the Regulation in order to check whether the goods are lawfully marketed in another Member State (Article 5(4) of the Regulation).

The mutual recognition declaration should be accompanied by supporting evidence necessary to verify the information contained in it (Article 5(4)(a) of the Regulation).

The use of the voluntary declaration does not prevent competent authorities of the Member State of destination from: (i) assessing goods to establish whether the legitimate public interests covered by the applicable national technical rule in their Member State are adequately protected in the light of the characteristics of the goods in question; or (ii) taking administrative decisions restricting or denying market access, provided that such decisions are justified.

The mutual recognition declaration should always contain accurate and complete information on the goods (recital 19 of the Regulation). It should be updated to reflect any changes, for example changes in the relevant national technical rules (recital 19 and Article 4(3) of the Regulation).

Changes in the national rules may also require changes to the goods. If the specific goods comply with the amended technical requirements, the goods should not be changed. However, if the goods become non-compliant with the national rules of the Member State where the goods are lawfully marketed as a consequence of the amendments of those rules, the goods will need to be modified to comply with the legislation of the Member State where they were lawfully marketed. The economic operator responsible for the declaration's content and accuracy is the one who signs the relevant part of the declaration (Article 4(2) of the Regulation).

Economic operators may choose not to supply the mutual recognition declaration. In this case, competent authorities may request the economic operators to provide documentation and information within at least 15 working days following the request (Articles 5(5) and (6) of the Regulation). The Commission considers that, for reasons of good administration and legal certainty, this request for documentation and information should be in writing. The documentation and information a competent authority may request should be necessary for assessing: (i) the characteristics of the goods or type of goods in question; and (ii) the lawful marketing of the goods in another Member State (Article 5(5) of the Regulation). However, in line with the principle of proportionality, competent authorities should not ask for more than is necessary to demonstrate the characteristics of the goods and that the goods were lawfully marketed. In that sense, requiring an economic operator to obtain a certificate of lawful marketing issued by a ministry or other administrative body in the Member State of origin could be an example of a disproportionate request for supporting evidence.

On test reports or certificates issued by a conformity assessment body, Article 5(8) of the Regulation states the following.

In carrying out the assessment under paragraph 1, the competent authorities of Member States of destination shall take due account of the content of test reports or certificates issued by a conformity assessment body that have been provided by any economic operator as part of the assessment. The competent authorities of Member States of destination shall not refuse test reports or certificates that were issued by a conformity assessment body accredited for the appropriate field of conformity assessment activity in accordance with Regulation (EC) No 765/2008 on grounds related to the competence of that body.

This means that when an economic operator has provided certificates by a conformity assessment body accredited for the appropriate field of conformity assessment in accordance with Regulation (EC) No 765/2008 of the European Parliament and of the Council ([22]), the competent authority of the Member State of destination should not require certificates from another conformity assessment body only on the grounds that it questions the competence of the conformity assessment body that issued the certificates.

([22]) 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).

3.4.1. *Content and structure of the declaration*

The annex to the Regulation sets out the structure of the mutual recognition declaration, which should always contain all the information specified in the annex (Article 4(1) of the Regulation).

The declaration is divided into two parts, both of which serve a specific objective.

— Part I provides information on the characteristics of the goods or type of goods and on the specific rules in the Member State where the goods are lawfully marketed.

— Part II provides information on the marketing of the goods or that type of goods in the Member State of origin. Supporting evidence for the information in this part could, amongst others, take the form of an invoice, a document with evidence of a sale, tax records, registrations, licences, notifications to/from authorities, certifications, or extracts from public records.

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

Part I

1. Unique identifier for the goods or type of goods: … [*Note: insert the goods identification number or other reference marker that uniquely identifies the goods or type of goods*]
2. Name and address of the economic operator: … [*Note: insert the name and address of the signatory of Part I of the mutual recognition declaration: the producer and, where applicable, its authorised representative, or the importer, or the distributor*]
3. Description of the goods or type of goods subject of the mutual recognition declaration: … [*Note: the description should be sufficient to enable the goods to be identified for traceability reasons. It may be accompanied by a photograph, where appropriate*]
4. Declaration and information on the lawfulness of the marketing of the goods or that type of goods

4.1. The goods or type of goods described above, including their characteristics, comply with the following rules applicable in … [*Note: identify the Member State in which the goods or that type of goods are claimed to be lawfully marketed*]: … [*Note: insert the title and official publication reference, in each case, of the relevant rules applicable in that Member State and reference of the authorisation decision if the goods were subject to a prior authorisation procedure*],

…or

the goods or type of goods described above are not subject to any relevant rules in … [*Note: identify the Member State in which the goods or that type of goods are claimed to be lawfully marketed*].

4.2. Reference of the conformity assessment procedure applicable to the goods or that type of goods, or reference of test reports for any tests performed by a conformity assessment body, including the name and address of that body (if such procedure was carried out or if such tests were performed): …

5. Any additional information considered relevant to an assessment of whether the goods or that type of goods are lawfully marketed in the Member State indicated in point 4.1: …
6. This part of the mutual recognition declaration has been drawn up under the sole responsibility of the economic operator identified under point 2.

Signed for and on behalf of:

(place and date):

(name, function) (signature):

Part II

7. Declaration and information on the marketing of the goods or that type of goods

7.1. The goods or that type of goods described in Part I are made available to end users on the market in the Member State indicated in point 4.1.

7.2. Information that the goods or that type of goods are made available to the end users in the Member State indicated in point 4.1, including details of the date of when the goods were first made available to end users on the market in that Member State: …

8. Any additional information considered relevant to an assessment of whether the goods or that type of goods are lawfully marketed in the Member State indicated in point 4.1: …

9. This part of the mutual recognition declaration has been drawn up under the sole responsibility of … [*Note: insert the name and address of the signatory of Part II of the mutual recognition declaration: the producer and, where applicable, its authorised representative, or the importer, or the distributor*]

Signed for and on behalf of:

(place and date):

(name, function) (signature):

3.4.2. *Language of the declaration*

The language of the declaration must be one of the official languages of the EU. However, if the declaration is in a language other than the languages required by the Member State of destination, the economic operator must translate the mutual recognition declaration into a language required by the Member State of destination (Article 4(1), sixth subparagraph, of the Regulation).

3.4.3. *Who may draw up the declaration?*

The provisions of the Regulation concerning the declaration ensure the necessary balance between: (i) providing all economic operators with the possibility of drawing up the declaration; and (ii) the respective economic operator assuming responsibility for the declaration or the parts of the declaration it draws up.

The producer of goods, or goods of a given type, is best placed to draw up the voluntary declaration. The producer may also mandate an authorised representative to draw up the declaration on its behalf and under its responsibility (Article 4(1), first subparagraph, of the Regulation). The importer or the distributor may also draw up the declaration if they can provide the evidence necessary to verify the information contained in the declaration (Article 4(1), fifth subparagraph, of the Regulation).

The producer (or its authorised representative, if empowered to do so) may fill in only the information in Part I of the mutual recognition declaration (e.g. type, description, characteristics of goods, applicable rule if any in the Member State where the goods are claimed to be lawfully marketed, conformity assessment procedure or test reports performed etc.). In such cases, the information in Part II of the declaration should be filled in by the importer or distributor (Article 4(1), fourth subparagraph, of the Regulation).

Economic operators who sign the mutual recognition declaration – or a part of it – are responsible for the content and accuracy of the information that they provide in the declaration. They are liable in accordance with national law, and when the declaration has to be translated, they are responsible for the correctness of the information they translate (Article 4(2) of the Regulation).

Economic operators must also ensure that the mutual recognition declaration is kept up to date at all times, reflecting any changes in the information that they have provided (Article 4(3) of the Regulation).

3.4.4. *What happens if the declaration is only partially complete?*

According to the third subparagraph of Article 4(1) of the Regulation, the mutual recognition declaration must follow the structure set out in Parts I and II of the annex and contain *all the information specified in the annex*.

Therefore, if the declaration is incomplete because it does not contain all the required elements, it should be considered invalid for the purpose of Article 5(4) of the Regulation. As a result, Article 5(5) and 5(6) of the Regulation will apply and the competent authority of the Member State of destination can request the information necessary for the assessment. The economic operator should be allowed at least 15 working days to comply following the request to submit the documentation and information necessary for the assessment.

3.4.5. *How and when can the declaration be used?*

The competent authority of the Member State of destination must inform the economic operator concerned 'without delay' when it intends to assess whether 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 (Article 5(1) of the Regulation).

At the same time, pursuant to Article 5(2) of the Regulation, the competent authority should indicate:

— the goods that are subject to the assessment;

— the applicable technical rule or prior authorisation procedure;

— the possibility of supplying a mutual recognition declaration.

The economic operator may choose to submit a mutual recognition declaration with the supporting evidence necessary to verify the information contained in it. This would be less burdensome for the economic operator since the competent authority should not require any other information or documentation from any economic operator to demonstrate that the goods are lawfully marketed in another Member State (Article 5(4) of the Regulation).

3.4.6. *How to submit documents*

The declaration and the supporting evidence must be submitted within a time limit that cannot be less than 15 working days following the request of the competent authority of the Member State of destination (Article 5(6) of the Regulation). The submission may be made either in paper or by electronic means or made available online according to the requirements of the Member State of destination (Article 4(4) of the Regulation).

3.5. **Assessment by the competent authority (Article 5(1) of the Regulation)**

A competent authority of the Member State of destination may assess goods to establish:

— whether the goods or goods of that type are lawfully marketed in another Member State;

— and, if so, whether the legitimate public interests covered by the applicable national technical rule of the Member State of destination are adequately protected, having regard to the characteristics of the goods in question.

Access to the market of the Member State of destination of goods lawfully marketed in another Member State can be restricted or denied only where:

1) the national technical rule of the Member State of destination pursues a legitimate public interest objective, and

2) the restriction or denial of access is **proportionate**, meaning that the measure is **appropriate** for securing the attainment of the objective and **necessary** (it does not go beyond what is necessary for attaining the objective).

Administrative decisions restricting or denying market access in respect of goods that are lawfully marketed in another Member State should not be based on the mere fact that the goods under assessment fulfil the legitimate public objective pursued by the Member State in a way different from the way in which goods in that Member State fulfil that objective (recital 5 of the Regulation). What does it mean that the goods fulfil the legitimate public objective in a different way? It means that goods could achieve the objective pursued by the national legislator even if, for example, they were tested by testing methods in the Member State of origin that are different from the method prescribed in the Member State of destination.

3.5.1. *Legitimate public interest grounds*

According to Article 36 TFEU, Articles 34 and 35 TFEU do not prevent prohibitions or restrictions on imports, exports or goods in transit justified on grounds of: (i) public morality, (ii) public policy or public security; (iii) the protection of health and life of humans, animals or plants; (iv) the protection of national treasures possessing artistic, historic or archaeological value; or (v) the protection of industrial and commercial property. However, such prohibitions or restrictions must not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.

In addition to the grounds listed in Article 36 TFEU, there are 'overriding reasons of public interest' or 'mandatory requirements' ([23]) developed by the Court. In *Cassis de Dijon* ([24]), the Court explained that an obstacle to the free movement of goods resulting from disparities between the national laws relating to the marketing of the products must be accepted in so far as those provisions may be recognised as being necessary to satisfy mandatory requirements relating in particular to the effectiveness of fiscal supervision, the protection of public health, the fairness of commercial transactions and consumer protection. The Court may recognise other grounds of justification. For example, protection of fundamental rights (e.g. protesters' freedom of expression and freedom of assembly ([25])), consumer protection ([26]), child protection ([27]) or the protection of the environment ([28]).

More information on legitimate public interest grounds is provided in the *Guide to the application of Treaty provisions governing the free movement of goods* ([29]).

3.5.2. *The principle of proportionality*

The decision must comply with **the principle of proportionality**. This means that the administrative decision must be appropriate for the purpose of achieving the objective pursued and not go beyond what is necessary to attain that objective.

In Case C-320/03, *Commission v Austria*, the Court stated that 'in order to establish whether such a restriction is proportionate having regard to the legitimate aim pursued in this case, namely the protection of the environment, it needs to be determined whether it is necessary and appropriate in order to secure the authorised objective' ([30]).

The proportionality of the national technical rule is the basis for demonstrating the proportionality of the administrative decision based on that rule. However, the means by which the proportionality of the administrative decision is to be demonstrated needs to be determined on a case-by-case basis (recital 27 of the Regulation).

The *Guide to the application of Treaty provisions governing the free movement of goods* contains useful information on the proportionality test.

The paragraphs below discuss some examples of the proportionality principle.

a) Is the measure appropriate to ensure that the intended objective is attained?

The Court assessed the **appropriateness** of measures to achieve the objective in the following cases among others ([31]).

([23]) The Court called them 'mandatory requirements' in *Cassis de Dijon*.
([24]) Judgment of 20 February 1979, *Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein,* Case 120/78 ECLI:EU:C:1979:42, paragraph 13.
([25]) Judgment of 12 June 2003, *Schmidberger,* C-112/00, ECLI:EU:C:2003:333: 'restriction of trade in goods between Member States is justified by the legitimate interest in the protection of fundamental rights, in this case the protesters' freedom of expression and freedom of assembly'.
([26]) Judgment of 22 September 2016, *European Commission v Czech Republic,* C-525/14, ECLI:EU:C:2016:714.
([27]) Judgment of 14 February 2008, *Dynamic Medien Vertriebs GmbH v Avides Media AG*, C-244/06, ECLI:EU:C:2008:85: prohibition of importation of Japanese cartoons called 'Anime' in DVD or video cassette format from the United Kingdom to Germany because these did not bear a label from that authority indicating the age from which the cartoons may be viewed, child protection being a justified base for the prohibition.
([28]) Judgment of 1 July 2014, *Ålands Vindkraft AB v Energimyndigheten,* C-573/12, ECLI:EU:C:2014:2037; Judgment of 15 November 2005, *Commission v Austria*, C-320/03, ECLI:EU:C:2005:684.
([29]) Guide to the application of Treaty provisions governing the free movement of goods, 2010, https://op.europa.eu/en/publication-detail/-/publication/a5396a42-cbc8-4cd9-8b12-b769140091cd
([30]) Judgment of 15 November 2005, *Commission v Austria*, C-320/03, ECLI:EU:C:2005:684, paragraph 85.
([31]) For more information, see Guide to the application of Treaty provisions governing the free movement of goods, 2010, https://op.europa.eu/en/publication-detail/-/publication/a5396a42-cbc8-4cd9-8b12-b769140091cd

— In *Ålands Vindkraft* the Court stressed that the use of renewable energy sources for the production of electricity is useful for the protection of the environment inasmuch as it contributes to the reduction in greenhouse gas emissions, which are among the main causes of climate change that the EU and its Member States have pledged to combat ([32]).

— The Court held in *Commission v Italy* (trailers) that a prohibition to use motorcycles towing trailers is appropriate for the purpose of ensuring road safety ([33]).

— The Court in *Dynamic Medien* held that there is no doubt that prohibiting the sale and transfer by mail order of image storage media which have not been examined and classified by the competent authority for the purpose of protecting young persons and which do not bear a label from that authority indicating the age from which they may be viewed constitutes a measure suitable to protect children against information and materials injurious to their well-being ([34]).

b) Is the measure necessary to attain that objective?

The administrative decision is proportionate if it is not only appropriate but also **necessary** to achieve the legitimate objective. In this part of the assessment, the question one should consider is: does the administrative decision go beyond what is necessary to achieve the legitimate objective? If there are less restrictive means to achieve the same objective, then the administrative decision goes beyond what is necessary. The examples below demonstrate which questions should be posed to assess the necessity of an administrative decision.

— In *Commission v Czech Republic*, the Court pointed out that, in connection with the fight against fraud to ensure the protection of consumers in its territory, Member States are entitled to consider that hallmarks affixed in the territory of third countries do not offer a level of protection of consumers equivalent to the hallmarks affixed by independent bodies in the territory of the Member States (except where the Member State of import from third countries, which has an equivalent system of hallmarking, carries out checks of the goods and the results meet the requirement of that Member State ([35])). The Court found, however, that the measure was not proportionate to the objective pursued, since the same objective could have been achieved by alternative, less restrictive measures. Firstly, the Czech authorities could have required documentary evidence from the importer to show the place where the hallmark in question was affixed and, as the case may be, the place where the precious metals concerned were put into free circulation and lawfully marketed in the EU. Secondly, the Czech authorities could have limited the refusal to recognise the WaarborgHolland hallmarks solely to circumstances in which an additional control of the precious metals by the Czech authorities is actually justified by the protection of consumers, in particular in cases of imports from third countries ([36]).

— In *Ålands Vindkraft*, a wind farm located in Finland was refused the Swedish award of electricity certificates because such certificates were reserved only for green electricity production installations located in Sweden. The Court, however, found the measure proportionate, explaining that it did not appear that Sweden acted in breach of the principle of proportionality merely by reserving a support scheme using green certificates exclusively for green electricity produced in the national territory. Member States have a mandatory national renewable energy target (their fair share of effort) and the only electricity they can count towards such target is the one produced in their installations. As a result, Sweden was legitimately able to consider that such a territorial limitation does not go beyond what is necessary to attain the objective – pursued both by Directive 2009/28/EC of the European Parliament and of the Council ([37]) and by the national scheme that falls within the scope of that Directive – of increasing the production and, indirectly, the consumption of green electricity in the European Union ([38]).

([32]) Judgment of 1 July 2014, *Ålands Vindkraft AB v Energimyndigheten*, C-573/12, ECLI:EU:C:2014:2037, paragraph 78.
([33]) Judgment of 10 February 2009, *Commission v Italy*, C-110/05, ECLI:EU:C:2009:66, paragraph 64.
([34]) Judgment of 14 February 2008, *Dynamic Medien Vertriebs GmbH v Avides Media AG*, C-244/06, ECLI:EU:C:2008:85, paragraph 47.
([35]) Judgment of 22 September 2016, *European Commission v Czech Republic*, C-525/14, ECLI:EU:C:2016:714, paragraphs 54 and 55.
([36]) Judgment of 22 September 2016, *European Commission v Czech Republic*, C-525/14, ECLI:EU:C:2016:714, paragraphs 65 and 66.
([37]) Directive 2009/28/EC of the European Parliament and of the Council of 23 April 2009 on the promotion of the use of energy from renewable sources and amending and subsequently repealing Directives 2001/77/EC and 2003/30/EC (OJ L 140, 5.6.2009, p. 16).
([38]) Judgment of 1 July 2014, *Ålands Vindkraft AB v Energimyndigheten*, C-573/12, ECLI:EU:C:2014:2037, paragraph 104.

— In the *Dynamic Medien* case, the Court assessed the necessity of the measure as follows: as far as the substantive scope of the prohibition was concerned, the law on the protection of young persons does not preclude all forms of marketing of unchecked image storage media. It is clear from the decision that it is permissible to import and sell such image storage media to adults by way of distribution channels involving personal contact between the supplier and the purchaser, which thus ensures that children do not have access to the image storage media concerned. In the light of those factors, it appears that the rules at issue in the main proceedings do not go beyond what is necessary to attain the objective pursued by the Member State concerned ([39]).

— In Case C-265/06, *Commission of the European Communities v Portuguese Republic*, the Court found that the fight against crime and ensuring road safety may constitute overriding reasons in the public interest capable of justifying a hindrance to the free movement of goods. Although the ban of affixing tinted film to the windows of passenger or goods vehicles 'does indeed appear to be likely to facilitate such inspection and, therefore, appropriate to attain the objectives of fighting crime and ensuring road safety, it does not follow that it is necessary to attain those objectives or that there are no other less restrictive means of doing so' ([40]). The necessity of the ban was further undermined when the authorities admitted that motor vehicles fitted from the outset with tinted windows within the limits laid down by Council Directive 92/22/EEC ([41]) are allowed on their territory. Furthermore, there is a wide range of tinted films (from transparent film to film which is almost opaque) which means that at least some films, namely those with a sufficient degree of transparency, permit the desired visual inspection of the interior of motor vehicles. Therefore, the Court concluded that the ban on tinted films in vehicles was excessive and therefore disproportionate with respect to the objectives pursued ([42]).

3.6. **Temporary suspension of market access (Article 6 of the Regulation)**

Where a competent authority of a Member State of destination is assessing goods before deciding whether to restrict or deny market access, that authority should not be able to take decisions to suspend market access, except where rapid intervention is required to prevent harm to the safety or health of persons, to prevent harm to the environment, or to prevent the goods from being made available in cases where the making available of such goods is generally prohibited on grounds of public morality or public security, including, for example, the prevention of crime (recital 29 of the Regulation).

In accordance with Article 6(1) of the Regulation, when carrying out an assessment of goods, the competent authorities of the Member State of destination may temporarily suspend the making available of those goods on the market in that Member State only if:

a) under normal or reasonably foreseeable conditions of use, the goods pose a serious risk to human safety or health or to the environment, including one where the effects are not immediate, which requires rapid intervention by the competent authority; or

b) the making available of the goods, or of goods of that type, on the market in that Member State is generally prohibited in that Member State on grounds of public morality or public security.

Where the competent authority of a Member State temporarily suspends market access, it should immediately notify the economic operator concerned, the Commission and the other Member States (Article 6(2) of the Regulation). If the reason for the temporary suspension is that, *under normal or reasonably foreseeable conditions of use, the goods pose a serious risk to human safety or health or to the environment, including a risk without immediate effects, which requires rapid intervention by the competent authority*, the notification must be accompanied by a detailed technical or scientific justification demonstrating why the case falls within the scope of that point (Article 6(2) of the Regulation).

([39]) Judgment of 14 February 2008, *Dynamic Medien Vertriebs GmbH v Avides Media AG*, C-244/06, ECLI:EU:C:2008:85, paragraph 48.
([40]) Judgment of 10 April 2008, *Commission v Portuguese Republic*, C-265/06, ECLI:EU:C:2008:210, paragraphs 38-41.
([41]) Council Directive 92/22/EEC of 31 March 1992 on safety glazing and glazing materials on motor vehicles and their trailers (OJ L 129, 14.5.1992, p. 11).
([42]) Judgment of 10 April 2008, *Commission v Portuguese Republic*, C-265/06, ECLI:EU:C:2008:210, paragraphs 38-48.

3.7. **Administrative decision (Article 5(9)-5(13) of the Regulation)**

On completion of an assessment of the goods, the competent authority of the Member State of destination may decide to take an administrative decision with respect to the goods that it has assessed (Article 5(9) of the Regulation).

As mentioned earlier, mutual recognition is not an absolute principle. However, sound justification is required for any exceptions to this principle. Market access for goods lawfully marketed in another Member State cannot be restricted or denied solely on the grounds that national rules set out different requirements for the goods concerned. If there is a genuine reason to restrict or deny market access, justification must be provided for any such decision.

Until now, administrative decisions have rarely set out the reasons for restricting or denying market access to goods lawfully marketed in another Member State.

Articles 5(10)-5(12) of the Regulation list the categories of information that should be supplied in the administrative decision.

The administrative decision must contain *the reasons* for the decision, which must be set out in a sufficiently detailed and reasoned manner to facilitate an assessment of its compatibility with the principle of mutual recognition and with the requirements of the Regulation (Article 5(10) of the Regulation). In particular, the administrative decision must include the following information (Article 5(11) of the Regulation):

a) the national technical rule on which the administrative decision is based;

b) the legitimate public interest grounds justifying the application of the national technical rule on which the administrative decision is based;

c) the technical or scientific evidence considered by the competent authority of the Member State of destination, 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 (if any) put forward by the economic operator concerned that are relevant for assessing whether the goods have been lawfully marketed and 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;

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.

For the purposes of Article 5(11) of the Regulation, 'legitimate public interest grounds' are defined as any of the grounds set out in Article 36 TFEU or any other overriding reasons of public interest (Article 3(14) the Regulation) ([43]).

The administrative decision must specify the remedies available under the national law of the Member State of destination and the time limits applicable to those remedies. It should also include a reference to the fact that economic operators can avail themselves of SOLVIT and the new problem solving procedure (Article 5(12) of the Regulation, see also Section 3.10).

The administrative decision restricting or denying market access must be notified without delay to the economic operator. The decision does not take effect before it has been notified to the economic operator (Articles 5(9) and 5(13) of the Regulation).

3.8. **Notifications to the Commission and the other Member States**

National competent authorities must notify the Commission and other Member States of:

— temporary suspensions (Article 6(2) of the Regulation);

— administrative decisions (Article 5(9) of the Regulation).

For the purposes of Article 5(9) and Article 6(2) of the Regulation, the Information and Communication System on Market Surveillance (ICSMS) should be used (Article 11(1) of the Regulation).

The Commission must use the information available in ICSMS for future evaluation of the Regulation (Article 14(2) of the Regulation).

([43]) See also Section 3.5.1.

Temporary suspensions must be immediately notified through ICSMS to the Commission and the other Member States (Article 6(2) of the Regulation).

Administrative decisions are to be notified through ICSMS to the Commission and other Member States no later than 20 working days after the decision is taken (Article 5(9) of the Regulation).

The notified temporary suspension or administrative decision should be uploaded into ICSMS.

In theory, if a measure notified through the Rapid Information System (RAPEX) ([44]) or the Rapid Alert System for Food and Feed (RASFF) ([45]) concerns goods that are not covered by the EU harmonisation legislation and that are being marketed lawfully in another Member State, that measure should also be notified under the Regulation, using the ICSMS system.

The Regulation is designed to release Member States from the burden of double notifications in cases where a measure requires notification under two systems. Article 7 therefore states that if an administrative decision or a temporary suspension is also a measure which is to be notified through RAPEX or RASFF, 'a separate notification to the Commission and the other Member States under this Regulation shall not be required' if the following conditions are met: a) the RAPEX or RASFF notification indicates that the notification also serves as a notification under Regulation (EU) 2019/515, and b) the supporting evidence satisfying the requirements set out in Regulation (EU) 2019/515 is provided.

The competent authority of the Member State of destination is responsible for uploading the documents required under the Regulation. As mentioned above, these documents are the administrative decision and the temporary suspension (accompanied by the detailed technical or scientific justification in cases where it is based on a serious risk to human safety or health or to the environment).

3.9. **Remedies against the administrative decision**

Any administrative decision taken by the competent authority of a Member State of destination under the Regulation must specify the remedies available under national law and the deadlines for using those remedies (Article 5(12) of the Regulation and recital 35 of the Regulation), so that an economic operator can appeal or bring proceedings against the decision. The available options for challenging such decisions depend on the remedies provided by national law (administrative instance of appeal, national courts, tribunals or other instances of appeal). In general, national judicial systems provide, either directly or after an administrative appeal, the possibility of bringing an appeal before a court or tribunal against the competent authority's administrative decision to restrict or deny market access.

Article 8 of the Regulation introduces a new problem-solving procedure to provide effective remedy and re-establish trust in mutual recognition. This new procedure is entrusted to the SOLVIT network.

3.10. **What is SOLVIT?**

SOLVIT is an existing network of centres set up by the Member States that aims to deliver fast, effective and informal solutions to problems individuals and businesses encounter when their EU rights in the single market are being denied by public authorities, based on Commission Recommendation 2013/461/EU on the principles governing SOLVIT ([46]).

SOLVIT is an informal, non-judicial problem-solving mechanism that provides an alternative to court proceedings. It provides practical solutions for individuals and businesses experiencing difficulties in cross-border situations associated with the single market and caused by a public authority. SOLVIT is free of charge and is provided by the national administration in each EU Member State, as well as in Iceland, Liechtenstein and Norway. The principles governing its operation are set out in Commission Recommendation 2013/461/EU, which states that each Member State is to provide a SOLVIT centre with sufficient resources to ensure that it can take part in the network ([47]).

The SOLVIT procedure may be triggered by economic operators affected by an administrative decision. Recommendation 2013/461/EU does not set any time limit for launching the SOLVIT procedure. However, if economic operators decide to use SOLVIT, it is advisable that they submit the administrative decision to SOLVIT as early as possible. As SOLVIT is an

([44]) In accordance with Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (OJ L 11, 15.1.2002, p. 4).
([45]) In accordance with Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).
([46]) Commission Recommendation 2013/461/EU of 17 September 2013 on the principles governing SOLVIT (OJ L 249, 19.9.2013, p. 10).
([47]) Section IV, point 2 of Recommendation 2013/461/EU.

informal mechanism, recourse to the SOLVIT procedure does not suspend any formal deadline to submit an administrative or judicial appeal, nor does it replace such appeals. If, during an ongoing SOLVIT procedure, an economic operator submits a judicial appeal, it is usual practice to notify the SOLVIT centre. The SOLVIT centre will stop the SOLVIT procedure and the mandate of the SOLVIT centre ends ([48]).

Where national systems provide for the possibility of an administrative appeal against the competent authority's administrative decision to restrict or deny market access before the authority responsible for supervising that competent authority (depending on the system applicable in the Member State concerned), some authorities decide to halt the procedure temporarily if a SOLVIT problem-solving procedure is under way. This enables the supervisory authority to take account of the SOLVIT process.

All SOLVIT cases are handled by two SOLVIT centres, the home centre and the lead centre ([49]). The home centre is typically located in the Member State of the complainant, while the lead centre is in the Member State of the authority about which a complaint has been made. The home centre is responsible for making a legal assessment of the problem and preparing the case before submitting it to the SOLVIT centre of the authority about which a complaint has been made ([50]). The lead centre is responsible for finding solutions for the applicants, including clarification of the applicable EU law, and should regularly inform the home centre about how the complaint is progressing ([51]).

SOLVIT centres use a secure online system for handling cases ([52]). This makes communication efficient and is conducive to full transparency. The Commission has access to the system, monitors the quality of the case handling, and offers assistance and clarifications in complex cases.

3.11. **SOLVIT and the problem-solving procedure under Article 8 of the Regulation**

The SOLVIT procedure described in Recommendation 2013/461/EU and the special problem-solving procedure provided by Article 8 of the Regulation are different. The main difference in these procedures is the possibility for the SOLVIT centres to request the Commission to issue an opinion.

The SOLVIT procedure described in Recommendation 2013/461/EU does not provide any possibility for SOLVIT centres to ask the Commission for an opinion. However, Article 8(1) of the Regulation provides that where an economic operator has initiated a SOLVIT procedure, the home centre or the lead centre can request the Commission to give an opinion to assist in solving the case. This specific procedure applies only in cases where the authorities have issued an administrative decision in accordance with Article 5 of the Regulation. It includes the possibility for a SOLVIT centre to request the Commission to assess whether the administrative decision is compatible with the principle of mutual recognition and the requirements of the Regulation (Article 8(1) and 8(2) of the Regulation). The problem-solving procedure under the Regulation involves longer deadlines than the usual SOLVIT procedure, to allow the Commission sufficient time to issue the opinion.

([48]) Section III, point 6 of Recommendation 2013/461/EU.
([49]) Section V.A, point 1 of Recommendation 2013/461/EU.
([50]) Section V.B, point 2 of Recommendation 2013/461/EU.
([51]) Section V.C, point 2 of Recommendation 2013/461/EU.
([52]) The SOLVIT online database is a stand-alone module in the Internal Market Information system. Given this technical integration, the rules set out in Regulation (EU) No 1024/2012 of the European Parliament and of the Council of 25 October 2012 on administrative cooperation through the Internal Market Information System and repealing Commission Decision 2008/49/EC (the 'IMI Regulation') (OJ L 316, 14.11.2012, p. 1) on the processing of personal data and of confidential information also apply to SOLVIT procedures. The SOLVIT Recommendation further specifies certain aspects of the processing of personal data in SOLVIT, in accordance with the IMI Regulation.

To make economic operators aware of the availability of the specific problem-solving procedure of the Regulation, all administrative decisions issued by national authorities under the Regulation must include a reference to the possibility for economic operators to use SOLVIT and the problem-solving procedure established by Article 8 of the Regulation (Article 5(12) of the Regulation; see also Section 3.7). For instance, the administrative decision could include a paragraph like the following.

'You may submit this decision to SOLVIT, under the conditions laid down in Recommendation 2013/461/EU. The home centre or the lead centre may request the Commission to give an opinion in order to assist in solving the case, in accordance with Article 8(1) of Regulation (EU) 2019/515.'

SOLVIT has always been available to economic operators facing problems in the single market. Other problems associated with marketing goods in another Member State, such as the lack of a reply from the competent authority, or a refusal to issue a decision, will continue to be handled by SOLVIT in the usual way. However, such problems will not trigger the specific problem-solving procedure set out in Article 8 of the Regulation.

3.12. **The Commission opinion in the context of the problem-solving procedure of Article 8 of the Regulation**

Where SOLVIT's informal approach fails and doubts remain about the compatibility of the administrative decision with the principle of mutual recognition, any of the SOLVIT centres involved may ask the Commission to issue an opinion (Article 8(1) of the Regulation). The purpose of the Commission's opinion is to allow it to assess whether the national administrative decision is compatible with the principle of mutual recognition and with the requirements of the Regulation (Article 8(2) of the Regulation). Among other things, the Commission should consider the documents and information provided as part of the SOLVIT procedure. It can request additional information or documents through the relevant SOLVIT centre (Article 8(3) of the Regulation).

Within 45 working days of receipt of the request for an opinion (which does not include the time necessary for the Commission to receive the above-mentioned additional information and documents) the Commission must complete its assessment and issue an opinion (Article 8(4) of the Regulation). This opinion should address only the issue of whether the administrative decision is compatible with the principle of mutual recognition and with the requirements of the Regulation (Article 8(2) of the Regulation). Where appropriate, the opinion should identify any concerns to be addressed in the SOLVIT case or make recommendations that may help solve the case (Article 8(4) of the Regulation). The Commission's opinion must be taken into account during the SOLVIT procedure (Article 8(6) of the Regulation).

The Commission communicates its opinion via the relevant SOLVIT centre to the economic operator concerned and to the competent authorities. It also notifies all Member States of the opinion via ICSMS (Article 8(6) of the Regulation). The economic operator may make use of the Commission's opinion referred to in Article 8(4) of the Regulation and make it available to any relevant third parties.

If the Commission is informed that the case has been solved during the assessment period, the Commission is not required to issue an opinion (Article 8(5) of the Regulation).

The fact that the Commission issues an opinion does not affect its powers under Article 258 TFEU (recital 40 of the Regulation).

3.13. **The role of Product Contact Points (Article 9 of the Regulation)**

The Regulation makes it far easier than before to market goods not covered by EU harmonisation rules in other Member States, but it also places more responsibility on economic operators. They have to be aware of relevant national rules not only in the Member State where they lawfully market their goods, but also in the Member State of destination, for example whether there is a prior authorisation procedure.

To make sure that economic operators are not left to their own devices in collecting product-related information in Member States, the Regulation facilitates the collection of this information through Product Contact Points. Under Article 9(1) of the Regulation, Product Contact Points are to provide their services in accordance with Regulation (EU) 2018/1724 of the

European Parliament and of the Council ([53]) (the Single Digital Gateway Regulation). Product Contact Points should be adequately equipped and resourced (Article 9(1) and recital 42 of the Regulation) so that they can play their important role in facilitating communication between national authorities and economic operators.

Product Contact Points must provide online information on (Article 9(2) of the Regulation):

a) the principle of mutual recognition and the application of the Regulation in the territory of their Member State, including information on the assessment of goods procedure under Article 5 of the Regulation;

b) the direct contact details of the competent authorities in their Member State, including the particulars of the authorities responsible for supervising the implementation of the national technical rules applicable in the territory of their Member State;

c) the remedies and procedures available in the territory of their Member State in the event of a dispute between the competent authority and an economic operator, including the problem-solving procedure set out in Article 8 of the Regulation.

Although Product Contact Points are responsible for making the most important data available on their websites (see Article 9(2) and recital 42 of the Regulation), they may also be contacted directly by economic operators or competent authorities of Member States, and must provide further information within 15 working days of receiving a request (Article 9(3) and 9(4) of the Regulation). They must provide this further information free of charge (Article 9(5) of the Regulation). Product Contact Points should perform tasks associated with providing any product-related information, including electronic copies of, or online access to, the national technical rules, without prejudice to the national rules governing the distribution of national technical rules (recital 42 of the Regulation).

National authorities can also contact and request information from Product Contact Points or authorities from another Member State (e.g. the Member State of origin/first lawful marketing) to verify the data provided by economic operators during the assessment of goods (see Articles 5, 9 and 10(3) of the Regulation). Product Contact Points may also be used to facilitate contacts between the relevant competent authorities (Article 10(3) of the Regulation).

However, Product Contact Points should not be required to provide copies of, or online access to, standards that are subject to the intellectual property rights of standardisation bodies or organisations (recital 42 of the Regulation).

Article 10 of the Regulation lays down rules on administrative cooperation that prescribe the most important fields in which the efficient cooperation of Product Contact Points and national authorities is necessary.

3.14. **Administrative cooperation (Article 10 of the Regulation)**

The Regulation strengthens Product Contact Points as one of the main channels of communication for mutual recognition and improves communication among Member States' competent authorities and Product Contact Points.

One of the forms of administrative cooperation provided for by the Regulation is the exchange of officials among Member States and the organisation of shared training sessions and awareness-raising programmes for authorities and businesses (Article 10(1)(c) of the Regulation). The Commission ensures cooperation among Member State authorities and Product Contact Points, while Member States ensure that their competent authorities and Product Contact Points participate in these activities (Articles 10(1) and 10(2) of the Regulation).

Administrative cooperation is especially important in assessing goods. Through the ICSMS system, the competent authorities of a Member State of destination may contact the competent authorities of the Member State of first lawful marketing if they need to check the information provided by the economic operator (Article 5(7) of the Regulation). The competent authorities should reply to such requests within 15 working days with any information relevant for verifying data and documents supplied by the economic operator during the assessment of goods concerned (Article 10(3) of the Regulation).

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

Product Contact Points may be used to facilitate contacts between the relevant competent authorities within the time limit of 15 working days for providing the requested information (Article 10(3) of the Regulation).

4. PRIOR ASSESSMENT OF NATIONAL TECHNICAL RULES – DIRECTIVE (EU) 2015/1535 AND THE SINGLE MARKET CLAUSE

Directive (EU) 2015/1535 is an important tool for preventing technical barriers to trade for products that are not covered by EU harmonisation legislation, or that are only partially covered by this legislation. It helps to ensure more and better mutual recognition by requiring Member States to notify the Commission of any draft technical regulations for products and information society services before they are enacted in national law.

Directive (EU) 2015/1535 and the Regulation apply at different stages in the life cycle of a technical regulation. Together, they ensure that national regulations do not create unjustified barriers to trade at any point in their life cycle.

The notification procedure under Directive (EU) 2015/1535 enables the Commission and the Member States to examine technical regulations for products and information society services that individual Member States are planning to adopt. It prevents the emergence of new technical barriers to trade by ensuring that national legislation is compatible with EU law and internal market principles. The procedure also enables businesses and other stakeholders to comment on notified drafts in the Technical Regulation Information System (TRIS) database.

A critical feature of the procedure is the legal consequences of non-compliance. The Court of Justice, in its judgment in Case C-194/94 ([54]), established the principle that failure to comply with the notification obligation (Article 5 of Directive (EU) 2015/1535) results in the technical regulations concerned being inapplicable, so that they are unenforceable against individuals.

The Court ruled that Directive (EU) 2015/1535 must be interpreted as having direct effect, which means that individuals should be able to rely on it directly in cases before national courts in which they are in opposition to the competent authorities. It also ruled that the national law was inapplicable because it had not been notified. The Court stated that if non-notified regulations remained enforceable, this would frustrate the objective and purpose of the Directive, tempting Member States to refrain from notifying. The judgment in Case C-194/94 has had major implications for the impact of Directive (EU) 2015/1535. In essence, it means that companies cannot be forced to comply with national technical rules that have not been notified.

Nevertheless, the fact that a technical regulation has been notified does not mean that its application is guaranteed to be compatible with EU law. A notified technical rule may still affect the free movement of goods, depending on how the national authorities apply the rule. This is where Regulation (EU) 2019/515 on mutual recognition comes into play, to ensure that the rule is applied correctly on a case-by-case basis, in a manner that complies with the principle of mutual recognition.

To raise awareness among 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 (recital 16 of the Regulation), to reduce the risk of these rules raising regulatory barriers to trade ([55]), and facilitate the application of that principle. In the notification procedure under Directive (EU) 2015/1535, the Commission regularly recommends, where appropriate, that the authorities of the Member State concerned include the single market clause in the notified draft, as set out in *The Goods Package: Reinforcing trust in the single market* ([56]). The following is a further clarified version of the clause.

Goods lawfully marketed in another Member State of the European Union or in Turkey, or originating and lawfully marketed in the Contracting Parties to the EEA Agreement are presumed to be compatible with these rules. The application of these rules is subject to Regulation (EU) 2019/515 of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State.

([54]) Judgment of 30 April 1996, *CIA Security v Signalson*, C-194/94, ECLI:EU:C:1996:172. See also Judgment of 26 September 2000, *Unilever*, C-443/98, ECLI:EU:C:2000:496, and Judgment of 19 December 2019, *Criminal proceedings against X*, C-390/18, ECLI:EU:C:2019:1112.

([55]) Report from the European Commission to the European Parliament, the Council and the European Economic and Social Committee on the operation of Directive (EU) 2015/1535 from 2014 to 2015 (COM(2017) 788 final, p. 5).

([56]) See the Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee of 19 December 2017, *The Goods Package: Reinforcing trust in the single market* (COM(2017) 787 final).

5. RELATIONSHIP BETWEEN REGULATION (EU) 2019/515 AND DIRECTIVE 2001/95/EC

Directive 2001/95/EC on general product safety ([57]) ('the GPSD') specifies that only safe products may be placed on the market (Article 3 of the GPSD) and lays down the product safety obligations of producers and distributors. It entitles the competent authorities to ban any dangerous products or to adopt any other appropriate measure (Article 8 of the GPSD).

The GPSD applies to consumer products, namely those that are subject to EU harmonisation legislation (where that legislation contains no specific provisions with the same objective as in Directive 2001/95/EC) and those that are not the subject of EU harmonisation (Articles 1(2) and 2(a) of the GPSD).

The Regulation applies to both consumer and non-consumer goods or aspects of goods that are not covered by EU harmonisation legislation.

5.1. Measures concerning products posing a risk to consumers' health and safety

The GPSD describes the procedure for competent authorities to apply appropriate measures if products pose a risk, such as the measures referred to in the GPSD's Article 8(1)(b) to 8(1)(f). Articles 5 and 6 of the Regulation do not affect the application of Article 8(1)(b) to 8(1)(f) and of Article 8(3) of Directive 2001/95/EC (see Article 2(6) of the Regulation).

5.2. Measures concerning consumer products posing other risks

Concerning consumer products, the Regulation applies where the competent authorities of a Member State intend to restrict or deny market access for a consumer product not covered by EU harmonisation legislation, lawfully marketed in another Member State, on the basis of a national technical rule and for reasons other than a risk to the health and safety of consumers. This could be the case, for example, when these authorities debar a product, although it does not pose a risk to the health and safety of consumers, from being marketed for environmental reasons.

([57]) OJ L 11, 15.1.2002, p. 4.