Summary of the mutual recognition regulation for businesses

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

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Introduction

This summary of the mutual recognition regulation complements the guidance document for the application of Regulation (EU) 2019/515[1]. It is intended for businesses interested in non-harmonised goods or the non-harmonised aspects of goods.

This summary contains answers to questions on the application of Regulation (EU) 2019/515, which should smoothen the application of the mutual recognition principle. The examples used in this material are inspired by the questions that the Commission services received from authorities and businesses.

Mutual recognition is applicable to goods in the Member State of destination that do not meet the requirements set out in the national technical rules of that Member State. If the goods are compliant with national technical rules, then there would be no need for mutual recognition. Consequently, if mutual recognition is applied properly, there should be goods on the market of a Member State that may not be fully compliant with the national technical rules, but are lawfully marketed in another Member State. Such goods are deemed to be compliant with the national technical rules in the Member State of destination, because they are lawfully marketed in another Member State. There are exceptions to this principle, and you will find some examples in this document.

We hope that this summary of the mutual recognition regulation will help you in applying the mutual recognition principle and hence the general principle of the free movement of goods within the EU.

[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. 1–18

Placing the goods on the market in another Member State under Regulation (EU) 2019/515

→ Should you inform the authorities when placing goods, lawfully marketed in another Member State, on the market in the former Member State?

The basic rule is that goods lawfully marketed in a Member State can be freely placed on the market of another Member State (without informing the authorities), except when prior authorisation is required in the Member State of destination.[2] The authorities in the Member States of destination should not take decisions to suspend market access during the assessment of the goods, except where rapid intervention is required.[3] If no such intervention is necessary, you may continue to make the goods available on the market unless you receive an administrative decision.

If the rules of the Member State of destination foresee a prior authorisation procedure being required for certain goods, you should apply for it.

Any decision to exclude or remove goods from the market solely on the grounds that they do not have prior authorisation does not constitute a decision to which Regulation (EU) 2019/515 applies. The rule that prescribes prior authorisation does not in itself constitute a technical rule within the meaning of the Regulation: it neither lays down certain characteristics of the goods, nor imposes other requirements that affect the life-cycle of the goods.

However, a decision rejecting the mandatory prior authorisation of the goods on the basis of a national technical rule is an administrative decision.

→ If the goods have a prior authorisation in the Member State of origin, do you have to repeat the whole prior authorisation procedure in the Member State of destination?

Member States should not refuse to accept test reports and certificates issued by other conformity assessment bodies in accordance with Union law. The authorities should avoid the duplication of tests and procedures which have been already carried out in another Member State and should take due account of the content of the test reports or certificates submitted.[4]

Consequently, the competent authorities in the Member State of destination must take into account all the documents collected during the course of the prior authorisation procedure in the Member State of origin. Therefore, the prior authorisation procedure should be less complicated, without duplication of controls, not too long and not too expensive.

→ What does it mean that the goods are 'lawfully marketed' in a Member State?

The goods are lawfully marketed in the Member State (the Member State of origin) if:

a. *<u>First option:</u>*

- the goods comply with the relevant national technical rules applicable in the Member State of origin; and
- the goods are made available to end users in that Member State.

Both criteria need to be met for the goods to fall under the mutual recognition principle.

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2 Article 5(3) of Regulation (EU) 2019/515.

3 Recital 29 of Regulation (EU) 2019/515.

4 Recital 30 and Article 5(8) of the Regulation (EU) 2019/515.

b. *Second option:*

- the goods are not subject to any national technical rule in the Member State of origin; and
- the goods are made available to the end users in that Member State.

If there are no rules in the Member State of origin applicable to the specific goods, it is sufficient that the goods are made available to end users in that Member State to be eligible for mutual recognition.

Is the country of origin of the goods relevant to establish whether goods are lawfully marketed in a Member State?

The origin of goods is not relevant for the definition of 'lawfully marketed'. As we saw, what is important is whether the goods comply with the technical rules in one of the Member States (if there are rules regarding the specific goods) and whether they are made available to end users in that Member State. If they fulfil both criteria, the goods can benefit from the principle of mutual recognition. For example, goods manufactured in a third country, which comply with the technical rules with one of the Member States and are made available in that Member State to end users are eligible for mutual recognition.

The requirement of the origin of the goods is only relevant when the goods are lawfully marketed in an EFTA State that is a Contracting Party to the EEA Agreement. These states are Iceland, Lichtenstein and Norway. The goods that are lawfully marketed in these states must also originate from a state that is one of the Contracting Parties to the EEA Agreement. More precisely, they must originate in an EU Country or in Iceland, Lichtenstein or Norway.

→ Where can you find out which rules apply to the goods in another Member State?

You can contact the Product Contact Points (PCPs) in any Member State or check their website. The PCPs will reply to your requests within 15 working days of receiving it. The PCPs contact details are available on the European Commission's website: https://ec.europa.eu/growth/single-market/goods/free-movement-sectors/mutual-recognition/contacts-list_en

Assessment of the goods based on Regulation (EU) 2019/515

→ How do you know if the authorities are assessing the goods that you placed on the market in the Member State of destination?

The authorities will contact you in writing (e.g. email) when they decide to assess the goods under Regulation (EU) 2019/515. They will inform you of the following[5]:

- which goods do they intend to assess;

[5] Article 5(1) of Regulation (EU) 2019/515.

- the national technical rule(s) or prior authorisation procedure that applies; and
- the possibility to supply the authorities with a mutual recognition declaration for the purposes of the assessment.

→ What is a mutual recognition declaration?

The mutual recognition declaration[6] is your statement, provided on a standardised template, that the goods are lawfully marketed in one of the Member States, for the purposes of mutual recognition. The template facilitates the assessment of the goods, as it contains all the information relevant for the assessment under Regulation (EU) 2019/515. You fill in and sign the template and you are responsible for the information provided in this declaration.

The standardised template is available here in all official languages of the EU: https://ec.europa.eu/docsroom/documents/40922

The template has two parts:

- Part I – description of the goods,
- Part II – information on placing the goods on the market

The mutual recognition declaration should always contain accurate and complete information on the goods. The declaration should therefore be kept up to date in order to reflect changes, for example changes in the relevant national technical rules[7].

It is possible to make the mutual recognition declarations publicly available online for the purposes of the assessment of the goods, if the type of goods is easily identifiable and the declaration is easily accessible.[8]

What happens if the technical rules applicable to the goods are modified in the Member State of origin and the goods are no longer compliant with those rules? Do you have to change the characteristics of the goods?

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.

→ Which supporting evidence should you submit to the authorities with the mutual recognition declaration?

The documents that you submit with the mutual recognition declaration should support the information stated there.

Any piece of evidence such as a product invoice, product label, catalogue with evidence of a date, sale or tax records, registrations, licences, notifications to/from the authorities, certifications,

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[6] More information available: https://europa.eu/youreurope/business/product-requirements/compliance/declaration-mutual-recognition/index_en.htm

[7] Recital 19 of Regulation (EU) 2019/515.

[8] Article 4(4) of Regulation (EU) 2019/515.

extracts from public records, etc. should be deemed suitable to demonstrate the lawful marketing of the product in another Member State.

If you submit the mutual recognition declaration during the course of the assessment of the goods with the supporting documents necessary to verify the information contained in it, the authority should not request any other additional proof from you. It should be sufficient to demonstrate that the goods are lawfully marketed in another Member State.[9]

→ What should you do if you receive information that market access to your goods are restricted or denied by a phone call?

According to Regulation (EU) 2019/515, only an individual administrative decision can have the legal effect of restricting or denying market access to goods lawfully marketed in another Member State.

As explained above, you may continue to make the goods available on the market in the Member State of destination unless you receive an administrative decision restricting or denying market access for those goods.[10] This rule does 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.

→ What is the purpose of and the procedure for the assessment of the goods?

As administrative decisions restricting or denying market access for goods that are already lawfully marketed in another Member State should be exceptions to the fundamental principle of the free movement of goods, it is necessary to ensure that such decisions observe the existing obligations that derive from the principle of mutual recognition.[11]

The purpose of the assessment under Regulation (EU) 2019/515 is to establish

- ✓ whether the goods are lawfully marketed in another Member State, and
- ✓ whether the legitimate public interests covered by the national technical rules are adequately protected. [12]

→ How the authorities assess the goods which have a different packaging or name in the Member State where they are lawfully marketed (Member State of origin) from the one in the Member State of destination?

Goods manufactured by one company for sale under another company's brand are called private label products.

If the private label product is only being placed on the national market without being first made available to end users in another Member State, Regulation (EU) 2019/515 will obviously not apply. However, if you can demonstrate that the goods are 'goods of that type' lawfully marketed in another Member State, mutual recognition is applicable.

For example, the same type of goods, e.g. a bread, produced by the same producer, based on the same recipe, containing the same ingredients but packaged differently depending on the Member State in which it is going to be marketed (e.g. blue material of the packaging in one state, green in

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9 Article 5(4) of Regulation (EU) 2019/515.

10 Article 5 (3) of the Regulation (EU) 2019/515.

11 Recital 28 of Regulation (EU) 2019/515.

12 Article 5(1) of Regulation (EU) 2019/515.

the other), with labelling in different languages or under a different name. You may change the packaging, for example, to comply with the language requirements in the Member State of destination instead of applying additional labelling to the goods. The colour of the packaging or the name can be different because of different consumer preferences in different countries or different brand names of the same product. In such cases, mutual recognition is applicable. Having the same packaging would probably facilitate the identification of the goods during the assessment, here, however, a deeper analysis (e.g. comparing the ingredients on the labelling of the blue and green packaging) is necessary.

We should also stress here, that in this situation you are also supposed to provide all the supporting evidence necessary to prove that the goods are of the same type, despite the differing name and packaging (e.g. the evidence could include a photo of both packaging types with a short explanation; a photo of the labelling from the two different packagings, where it is visible that all the ingredients are the same).

The administrative decision

The basis for the administrative decision is the national technical rule applicable in the Member State of destination. The direct or indirect effect of the administrative decisions is to restrict or deny market access. The notion of administrative decision includes any administrative step that is based on the national technical rule and that has the same or substantially the same legal effect, i.e. to restrict or deny market access.[13]

The administrative decision should describe in sufficient detail the reasons for denying or restricting market access. It allows the assessment of whether the decision is compatible with the principle of mutual recognition and with Regulation (EU) 2019/515. In particular, the administrative decision must include[14]:

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

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

c) the technical or scientific evidence that the competent authority considered, including, any relevant developments in the state-of-the-art that have occurred since the national technical rule came into force;

d) a summary of any arguments that you put forward and are relevant for the assessment on whether the goods are lawfully marketed and on whether the legitimate public interest covered by the applicable national technical rule is adequately protected, taking into account the characteristics of the goods in question; and

e) the evidence demonstrating that the administrative decision is appropriate for achieving the objective pursued and that it does not go beyond what is necessary to achieve that objective.

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13 Article 2(1) of Regulation (EU) 2019/515.

14 Article 5(10) and (11) of Regulation (EU) 2019/515.

The administrative decision must specify the remedies available under the national technical rule and the time limits applicable to those remedies. It must also refer to the possibility for economic operators to use SOLVIT and the problem solving procedure laid down in Regulation 2019/515[15].

→ What are your options if you do not agree with the reasons listed in the administrative decision?

The administrative decision will inform you of the remedies available under the national legal system and the possibility to use the SOLVIT procedure.

If you are not satisfied, you should submit the administrative decision to SOLVIT, as soon as possible. Under Regulation (EU) 2019/515 the SOLVIT problem-solving procedure aims at providing a business friendly alternative for economic operators wishing to challenge administrative decisions restricting or denying market access to goods. The SOLVIT problem solving procedure may lead to a request of an opinion from the European Commission.

[15] Article 5(12) of Regulation (EU) 2019/515.