The application of the mutual recognition regulation to food supplements

- **Training material for authorities -**

Introduction

This training material complements the guidance document for the application of Regulation (EU) 2019/515[1]. It is intended for inspectors and other officials of the national authorities who assess food supplements.

The training material 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 training material are inspired by the questions that the Commission services received from authorities and businesses engaged in the area of food and food supplements.

Mutual recognition is applicable to goods in your Member State 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 training material 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

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

Should the economic operator inform your 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] You 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, the economic operators may continue to make the goods available on the market unless they receive an administrative decision.

If the rules of your Member State foresee a prior authorisation procedure being required for certain goods, economic operators 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 your national technical rule is an administrative decision and should be notified in the Information and Communication System for Market Surveillance (ICSMS).

What should you do when you intend to assess the goods?

First, as Regulation (EU) 2019/515 applies to goods or aspects of goods that are not exhaustively covered by Union harmonisation rules, you should make sure that the goods (or an aspect of the goods) fall outside of these rules.

- Vitamins and minerals, and the specific chemical forms of these, permitted for use in food supplements are harmonised by Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements[4]. However, the maximum and minimum amounts of vitamins and minerals present in food supplements per daily portion consumed have not yet been harmonised. Regulation (EU) 2019/515 will therefore apply to these aspects until they have been harmonised by Union legislation. Regulation (EU) 2019/515 will also apply to the purity criteria for substances listed in Annex II, where these are not specified in other items of Union legislation (for example in the additive legislation).

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

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

4 Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements, OJ L 183, 12.7.2002, p. 51–57. Current consolidated version: 26/07/2017.

- Labelling, presentation and advertising are harmonised by Articles 6 to 9 of Directive 2002/46/EC as well as by Regulation (EU) No 1169/2011 on the provision of food information to consumers (FIC Regulation)[5].

- Regulation (EC) No 1924/2006[6] on nutrition and health claims made on foods lays down conditions for the use of nutrition and health claims on the packaging of things such as food supplements. This Regulation is very important in a sector like this, in which claims, and in particular health claims, are a favoured means of communication with consumers. The decisive criterion for the use of a health claim is that the claimed effect for a nutrient or substance is based on scientific evidence.

- The general principles of food safety are laid down in Regulation (EC) No 178/2002[7]. These principles cover not only any product defined as a 'foodstuff' but also any substance introduced into the food chain for the purposes of manufacturing a foodstuff, irrespective of the existence of specific provisions for that substance. Accordingly, all the provisions of Regulation (EC) No 178/2002 apply directly to the manufacture and ingredients of food supplements.

- Some of the food supplements or their ingredients may be considered as 'novel food' or 'novel ingredients' within the meaning of Regulation (EU) 2015/2283[8] on novel foods. This Regulation covers all foods and food ingredients which had not been used for human consumption to a significant degree within the Union before 15 May 1997.

Does a national rule requiring a notification of food supplements to the national authorities constitute a technical rule?

Article 10 of Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements specifies that Member States may require the manufacturer or the person placing the product on the market to notify the competent authority by submitting a model of the label used for the product.

Consequently, such notification is already the subject of harmonisation at Union level.

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5 *Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004OJ L 304, 22.11.2011, p. 18–63, Current consolidated version: 01/01/2018.*

6 *Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods, OJ L 404, 30.12.2006, p. 9–25, Current consolidated version:* 13/12/2014.

7 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. 1-24. Current consolidated version: 26/07/2019.

8 Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001, OJ L 327, 11.12.2015, p. 1–22.

How to treat products that are categorized as foodstuff in the Member State of origin, but fall into the category of medicinal products in your Member State?

The CJEU held in its judgment *Orthica*[9] that a product which constitutes a medicinal product within the meaning of Directive 2001/83 relating to medicinal products for human use[10] may be imported into another Member State only upon acquisition of a marketing authorisation issued in accordance with the provisions of that Directive, even where it is lawfully marketed as a foodstuff in another Member State.

Second, after you conclude that the assessment of the goods in question fall under Regulation (EU) 2019/515, you must contact the economic operator without delay, in writing (e.g. email), and inform them of the following[11]:

- which goods do you intend to assess;
- the national technical rule(s) or prior authorisation procedure that applies; and
- the possibility to supply you with a mutual recognition declaration[12] for the purposes of the assessment.

How to assess the goods which have a different packaging or name in your Member State from the one in the Member State of origin?

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 your national market without being first made available to end users in another Member State, Regulation (EU) 2019/515 will obviously not apply. However, if the economic operator demonstrates 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 the other), with labelling in different languages or under a different name. The producer may change the packaging, for example, to comply with the language requirements in your Member State 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.

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9 *HLH Warenvertriebs GmbH* and *Orthica BV* (C-299/03 and C-316/03 to C-318/03) v *Bundesrepublik Deutschland*.

10 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use; OJ L 311, 28.11.2001, p. 67–128, Current consolidated version: 26/07/2019

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

12 The standardized template of the mutual recognition declaration in all official languages is available here: https://ec.europa.eu/docsroom/documents/40922.

We should also stress here, that in this situation the economic operator is 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).

How can you verify the information submitted by the economic operator?

For the purposes of notifying administrative decisions restricting or denying market access, allowing communication between Product Contact Points and ensuring administrative cooperation, Member States have access to ICSMS.[13]

If you receive a voluntary mutual recognition declaration during the course of the assessment of the goods with the supporting documents necessary to verify the information contained in it, you should not request any other additional proof from the economic operator. It should be sufficient to demonstrate that the goods are lawfully marketed.[14]

However, in case you would like to verify whether the information provided in the mutual recognition declaration is correct (e.g. whether the technical rule to which the economic operator refers is the latest technical rule in the Member State of origin), you can contact the competent authority in that Member State through ICSMS. If you do not know which authority is the competent authority in that Member States for a specific area of competence, you can contact the Product Contact Point in that Member State, again using ICSMS, and ask them to provide you with the contact details of the responsible competent authority. Both, competent authorities and Product Contact Points should reply within 15 working days to your request sent through the communication module of ICSMS[15]. In case they do not answer in that period of time, they will receive a reminder from the system to send you a reply.[16]

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

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.[17]

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. [18]

Step-by-step approach for the assessment under the mutual recognition principle

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13 Recital (44) of Regulation (EU) 2019/515.

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

15 More information on the communication module of ICSMS is available here: https://webgate.ec.europa.eu/fpfis/wikis/display/ICSMS/Communication+Module?preview=/532811175/532811207/Communication%20Module%20-%20User%20guide.pdf

16 Article 5(7) and 10(3) of Regulation (EU) 2019/515.

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

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

First part of the assessment: Are the goods that do not comply with the national rules lawfully marketed in the Member State of origin?

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

a. *First option:*

- the goods comply with the relevant national technical rules applicable in a Member State; 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.

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 a 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 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.

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? Does the economic operator 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.

Second part of the assessment: Is the legitimate public interest covered by your technical rule adequately protected?

The following questions may help to establish whether the legitimate public interest covered by the technical rule that you apply is adequately protected:

- What is the legitimate public interest covered by the national technical rule in your Member State?

This is the reason why the specific rule for the goods is introduced. For example, the protection of public health, fiscal supervision, the protection of the environment, consumer protection.

- How is this legitimate public interest covered by the applicable national technical rules in your Member State?

You identify the requirements set out in the national technical rule related to either: (i) the characteristics of the goods; or (ii) the life-cycle of the goods after they have been made available on the market (e.g. use, recycling, etc.).

- Do the characteristics of the assessed goods adequately protect and achieve the legitimate public interest covered by the national technical rule?

As has been described, the assessed goods are not compliant with the national technical rules of your Member State, otherwise mutual recognition would not be invoked. However, you should assess whether the element that is missing in the assessed goods and which makes them non-compliant with the national technical rules is such that market access to the assessed goods should be restricted or denied. It is important to bear in mind that according to the mutual recognition principle, goods lawfully marketed in another Member State are presumed to be compatible with your national technical rules, even if they do not entirely comply in reality. A decision to restrict or deny market access to such goods should be an exception to the fundamental principle of free movement of goods. Where the public interest is adequately protected even if the goods do not comply with some elements of your national technical rule, market access to those goods should be granted.

- What to do if, regarding the characteristics of the assessed goods, you consider that the legitimate public interests covered by your national technical rule is not adequately protected?

When assessing the goods, you should consider any technical or scientific evidence relevant for the assessment, taking into account the characteristics of the goods under assessment.

If you conclude that the legitimate public interest is not adequately protected, you should identify the measure that is the least restrictive from the perspective of the free movement of goods. If you decide to take an administrative decision restricting or denying market access to the goods, the decision should contain all the elements set out in Article 5(11) of Regulation (EU) 2019/515.

How to make sure that the administrative decision is proportionate?

The proportionality of the application of the national technical rule to the product should be done on a case-by-case basis.[19]

The assessment should be based on the characteristics of the goods. The CJEU held that the administrative practice is disproportionate when it 'systematically prohibits the marketing of all foodstuffs to which vitamins and minerals have been added, without distinguishing according to the different vitamins and minerals added or according to the level of risk which their addition may possibly pose to public health'[20].

If, having regard to the characteristics of the goods, the legitimate public interest is not adequately protected, access to the market may be restricted or denied.

A prohibition of placing the goods on the market might be appropriate to achieve the objective of public interest, but if the same objective can be achieved by measures that are less restrictive from the perspective of free movement of goods, such prohibition is not necessary. The measure that is not necessary is not proportionate.

How to proceed in case of a foodstuff whose marketing is prohibited in your Member State because its content in nutrients exceeds the maximum amount set by the national technical rules? Should the marketing of such foodstuffs be allowed based on the principle of mutual recognition?

The marketing of that foodstuff should be permitted in your Member State based on the principle of mutual recognition. Nonetheless, the application of the national technical rule might be justified on public interest grounds (protection of public health). The application to obtain the authorisation to market such supplements may be refused by the competent national authorities only if those supplements pose a genuine risk to public health. The assessment should be based on a comprehensive scientific assessment of the genuine risk to public health.

The prohibition of marketing goods that are lawfully marketed in another Member State is one of the most restrictive measures that can be taken. Therefore, denying market access to such goods should be the last resort when there are no other less restrictive measures, such as labelling, to achieve the public interest by other means.

The administrative decision

The basis for the administrative decision is the national technical rule applicable in your Member State. The direct or indirect effect of the administrative decision is to restrict or deny market access. The notion of administrative decision includes any administrative step that is based on your national technical rule and that has the same or substantially the same legal effect, i.e. to restrict or deny market access.[21]

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[22]:

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

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19 Recitals 27-28, Article 5(1) of Regulation (EU) 2019/515.

20 *Commission v Kingdom of Denmark*, Case C-192/01, ECLI:EU:C:2003:492, para 55.

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

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

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 your 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 put forward by the economic operator concerned that are relevant for the assessment on whether the goods are lawfully marketed and on whether the legitimate public interest covered by your applicable national technical rule are 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.

The administrative decision must specify the remedies available under your 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[23].

How should you notify the administrative decision?

You should notify the administrative decision to the economic operator without delay. You should notify the administrative decision to the Commission and to the other Member States no later than 20 working days after you took it.[24]

You can find the User's Guide for Inspectors here: https://webgate.ec.europa.eu/icsms_internal/secure/docs/info/manual/ICSMSUsersGuide-Inspectors_EN.pdf

In case your authority does not have access to ICSMS, you should contact the National Administrator for ICSMS or GROW-ICSMS@ec.europa.eu.

For more information you can contact GROW-MUTUAL-RECOGNITION@ec.europa.eu.

Is there any sanction if the competent authority does not notify the administrative decision in ICSMS?

The CJEU held in its judgment of *Airbnb Ireland*[25] that a Member State's failure to fulfil its obligation to give notification of a measure restricting the freedom to provide an information society service provided by an operator established on the territory of another Member State, renders the measure unenforceable against individuals. Correspondingly, the Court held that an individual may oppose the application of restrictive measures of a Member State placed upon them that restrict the freedom of that individual to provide an information society service which that individual provides from another Member State, where those measures were not notified in accordance with the E-Commerce Directive.

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

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

25 *Airbnb Ireland,* Case C-390/18, ECLI:EU:C:2019:1112.

By analogy, it is possible that the absence of a notification of an administrative decision via ICSMS to the Commission and to other Member States might render the measure unenforceable against individuals and would allow for economic operators to oppose the application of that administrative decisions.