food supplements europe

Guidelines on how to apply the new Mutual Recognition Regulation (EU) 2019/515 to food supplements in the EU

April 2021

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1. The Principle of Mutual Recognition

A historic perspective

One of the key achievements of the European Union (EU) is the principle of 'free movement of goods', set out in Articles 34-36 of the Treaty of the Functioning of the European Union (TFEU)[1]. This enables companies to market their products in all EU Member States irrespective of national borders and despite national legislation in place.

The principle of 'Mutual Recognition', established by the Court of Justice of the EU (CJEU) ever since the Dassonville[2] and Cassis de Dijon[3] rulings, obliges a Member State to accept on its territory products which are not subject to European harmonisation but are lawfully marketed in another Member State[4]. Member States can only object to such marketing on the basis of a limited and well-defined number of grounds.

Nevertheless, as many economic operators in the area of food supplements have experienced, in practice the application of Mutual Recognition is far less straight forward. It is not well understood by companies and is often not applied correctly by Member States, despite numerous efforts by the European Commission (EC) to make economic operators and Member States aware of this fundamental right.

Because of these difficulties, in 2008 the EC adopted Regulation (EC) No 764/2008[5], with the aim to establish a legally binding procedure to be followed in cases where Mutual Recognition is denied by a Member State.

This legislation, however, did not live up to its expectations. An evaluation carried out between 2014 and 2016[6] showed that Regulation (EC) No 764/2008 had limited effect in facilitating the application of Mutual Recognition. The requirement to notify administrative decisions restricting or denying market access to the EC was rarely complied with, the procedure did not work and in cases where the Member State continued to refuse Mutual Recognition, there was no procedure to help companies to solve their issue.

In 2019 the EC therefore adopted Regulation (EU) 2019/515[7] to replace Regulation (EC) No 764/2008, which will apply from 19 April 2020.

These guidelines are intended to explain the main principles and help economic operators to assess in which cases Mutual Recognition is applicable to food supplements and how they can maximise their chances of success when challenged by a national authority denying Mutual recognition.

These guidelines should be read together with Regulation (EU) 2019/515 and guidance published by the EC on its website.[8]

1 Treaty of the Functioning of the European Union. Current consolidated version: 01/03/2020
2 Judgment of the Court of 11 July 1974 in Case 8/74 – Dassonville. EU:C:1974:82
3 Judgment of the Court of 20 February 1979 in Case 120/78 - Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein. EU:C:1979:42
4 And EFTA States that are Contracting Parties to the EEA Agreement: Iceland, Liechtenstein and Norway
5 No longer in force but replaced by Regulation (EU) 2019/515
6 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32008R0764&qid=1610971718530
7 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32019R0515&qid=1610971852719
8 https://ec.europa.eu/growth/single-market/goods/free-movement-sectors/mutual-recognition_en

1. Regulation (EU) 2019/515 at a glance:

Regulation (EU) 2019/515 defines and clarifies the principle of Mutual Recognition as laid down in Articles 34-36 TFEU.

It defines the **rights and obligations** in relation to the Mutual Recognition principle for competent authorities and economic operators when selling products in another EU Member State.

It includes:

- a **well-defined assessment procedure** to be followed by competent authorities when assessing products;
- the obligatory elements to be included in an **administrative decision** that restricts or denies market access;
- a **voluntary 'Mutual Recognition Declaration'**, which economic operators can use to demonstrate that their products are lawfully marketed in another Member State;
- a **business-friendly problem solving procedure**, based on SOLVIT, that includes the possibility of an assessment from the EC on the compatibility of a decision restricting or denying market access with EU law;
- principles for **stronger administrative cooperation** between the Member States to improve the application of the Mutual Recognition principle, for instance through the Information and the Communication System for Market Surveillance (ICSMS);
- more information to economic operators through reinforced 'product contact points' (PCP) and the **'single digital gateway'**.

Guidelines to clarify a number of aspects of this new legislation by the Commission are also under development. A general guideline for the application of Regulation (EU) 2019/515 [9] was published in March 2021.

NOTE: In relation to the previous legislation (Regulation (EC) No 764/2008), the following guidelines were available, which may still be relevant to certain aspects of the new regulation:

- The relationship between the Regulation 764/2008 and Directive 98/34/EC on the provision of information in the field of technical standards and regulations [10]
- The concept of 'lawfully marketed' in the Regulation 764/2008 [11]
- The application of the Regulation 764/2008 to articles of precious metals [12]
- The relationship between the Regulation 764/2008 and Directive 2001/95/EC on general product safety [13]
- The application of the Regulation 764/2008 to food supplements [14]
- The application of the Regulation 764/2008 to narcotic drugs and psychotropic substances [15]
- The application of the Regulation 764/2008 to prior authorisation procedures [16]
- The application of the Regulation 764/2008 to weapons and firearms [17]
- The application of the Regulation 764/2008 to fertilisers and growing media [18]
- The application of the Regulation 764/2008 to non-CE-marked construction products [19]

9 https://ec.europa.eu/docsroom/documents/44930
10 https://ec.europa.eu/docsroom/documents/5801/
11 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52013DC0592
12 https://ec.europa.eu/docsroom/documents/5806/
13 https://ec.europa.eu/docsroom/documents/5807
14 https://ec.europa.eu/docsroom/documents/13481
15 https://ec.europa.eu/docsroom/documents/5821
16 https://ec.europa.eu/docsroom/documents/5822
17 https://ec.europa.eu/docsroom/documents/5824
18 https://ec.europa.eu/docsroom/documents/5825
19 https://ec.europa.eu/docsroom/documents/5881

2. Overview of the process of Mutual Recognition

When placing a food supplement that is lawfully placed on the market in another Member State, an economic operator must be aware of its rights and obligations to ensure this can be done in compliance with Mutual Recognition and Regulation (EU) 2019/515.

The three key principles are:

1. Mutual recognition is the rule and denial of Mutual Recognition the exception.
2. An economic operator can benefit from Mutual Recognition if the following three conditions are met:
    a. The product, its composition or other aspects is not subject to harmonised EU legislation.
    b. The product is lawfully marketed in another EU Member State, meaning it complies with national legislation and is made available to end users.
    c. All necessary legal procedures for placing the product on the market in the Member State of destination have been complied with (e.g. notification).
3. A Member State can only deny Mutual recognition by means of an administrative decision. The burden to justify this denial lies with the Member State.

To maximise the chances of success of having Mutual Recognition applied to food supplements, it is recommended that economic operators verify the following:

A. Ensure that Mutual Recognition applies

- The issue must relate to a non-harmonised aspect of the product. Examples of such areas for food supplements are given in these guidelines.
- The product must be legally marketed in another Member State.
- The product must have been notified in those Member States that require notification and any applicable procedures foreseen by national legislation followed.

B. Complete the voluntary Mutual Recognition Declaration to prove the lawful marketing of the product in another Member State

C. If informed by the Member State that the product is being assessed

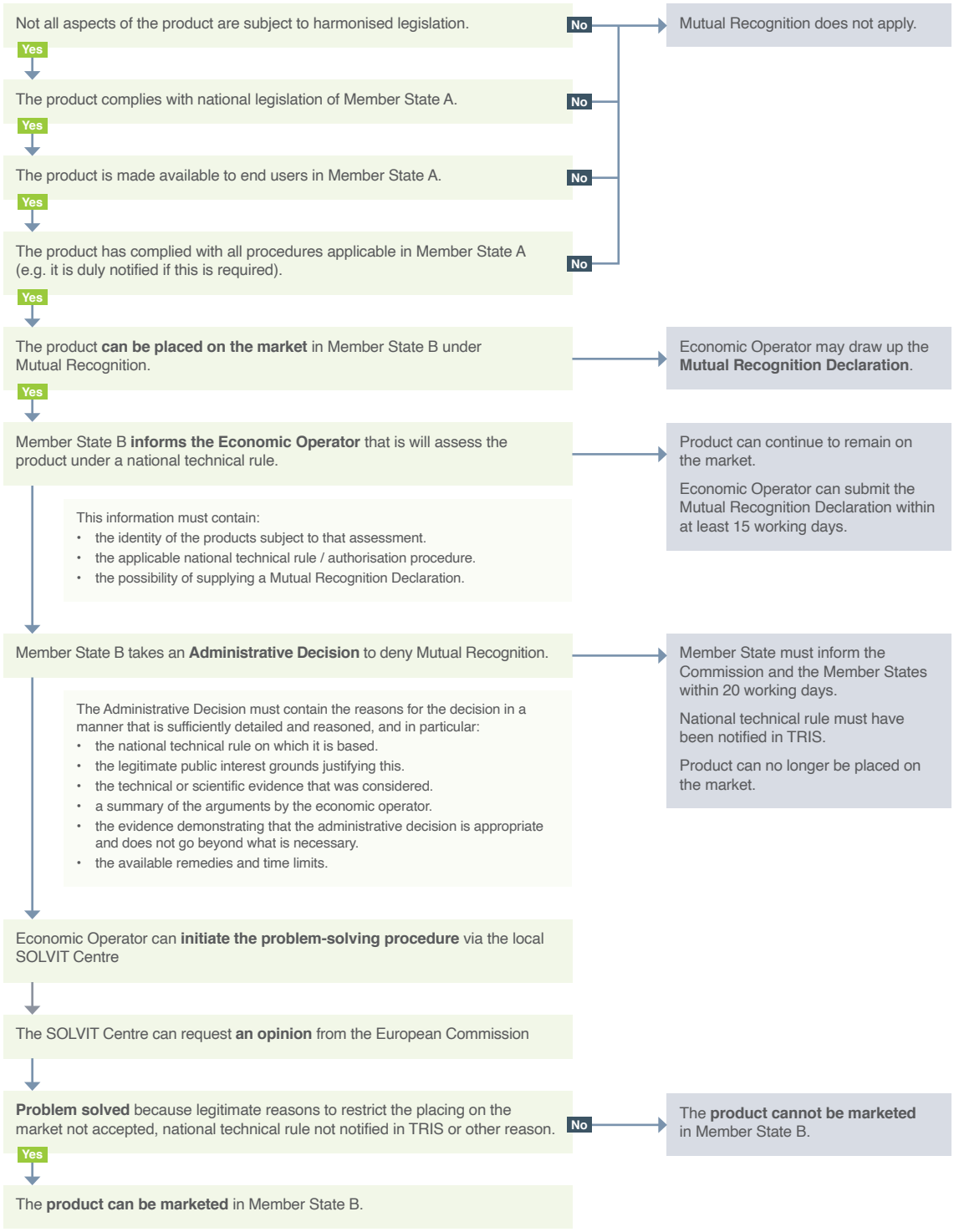
- Reply by asking to be informed the reasons for a possible denial of Mutual Recognition and to be able to provide information in reply to these reasons.

D. When informed of a decision that denies Mutual Recognition

- Check if this decision is an administrative decision and contains all required information, including the reason, set out in a sufficiently detailed and reasoned manner, for the denial of Mutual Recognition.
- Check if the national rules that justifies the denial has been notified in the TRIS system.
- Consider submitting the decision to the national SOLVIT Centre.
- During this procedure, consider asking the SOLVIT Centre to request an opinion from the EC.

These steps are addressed in the next sections and summarised in figure 1.

Figure 1. The Mutual Recognition process at a glance



3. Conditions for Mutual Recognition to apply to food supplements

Mutual Recognition applies to food supplements when the placing on the market is restricted or denied by a Member State because of national legislation, while this food supplement is lawfully marketed in another Member State.

In fact, any decision by a Member State to restrict or deny market access for food supplements that are already lawfully marketed in another Member State should be the exception to the fundamental principle of the free movement of goods.

Nevertheless, it is important to check if such a decision could be challenged under Mutual Recognition.

A legitimate Mutual Recognition case must comply with all of the following criteria:

i) The subject of the restriction must cover a non-harmonised aspect of the product;

ii) The product must have been lawfully marketed in another Member State;

iii) The placing of the product on the market must have complied with any procedure that is applicable, e.g. the product must have been duly notified where this is required;

iv) The placing of the product on the market must have been denied or restricted by an administrative decision, based on a national technical rule.

If the above criteria are met, Mutual Recognition should apply and the provisions and problem solving procedure of Regulation (EU) 2019/515 can be applied. If one of the criteria is not complied with, Mutual Recognition cannot however apply.

1. The aspect for which market access is restricted or denied must be non-harmonised

The principle:

Mutual Recognition can only apply to aspects of a food supplement that are not harmonised at EU level.

Differences in interpretation or application of harmonised legislation do not fall within the scope of Mutual Recognition.

Food supplements are subject to three types of legislation:

- Harmonised EU legislation applicable to all foods.
- Harmonised legislation relating to those specific aspects of food supplements regulated by Directive 2002/46/EC, e.g. the vitamins and minerals that may be added to food supplements and the permitted nutritional substances.
- National legislation.

The table below presents a non-exhaustive overview of the main pieces of EU legislation that apply to food supplements and the aspects that are subject to harmonisation.

Legislation	Harmonised	Not harmonised and thus, subject to Mutual Recognition
Directive 2002/46/EC [20] on the approximation of the laws of the Member States relating to food supplements	• The vitamins and mineral forms that are permitted in food supplements. • Specific labelling requirements for food supplements.	• Maximum and minimum levels of vitamins and minerals. • Other substances with a nutritional or physiological effect. • Conditions of use (e.g. restrictions, labelling statements, maximum levels, etc).
Regulation (EC) No 1924/2006 [21] on nutrition and health claims made on foods	• Nutrition and health claims and their conditions of use.	• Health claims that are still on hold (mostly for botanicals).
Regulation (EC) No 1925/2006 [22] on the addition of vitamins and minerals and of certain other substances to foods	• Substances that are prohibited, restricted or under scrutiny.	• All other provisions do not apply to food supplements as these are regulated by Directive 2002/46/EC. • The provisions about vitamins and minerals only apply to foods other than food supplements.
Regulation (EU) No 1169/2011 [23] on the provision of food information to consumers	• General labelling requirements applicable to all foods, including food supplements.	• Specific labelling provisions for food supplements in addition to those included in Directive 2002/46/EC that applies without prejudice to Regulation (EU) No 1169/2011.
Regulation (EU) 2015/2283 [24] on novel foods Commission Implementing Regulation (EU) 2017/2470 [25] establishing the Union list of novel foods	• Authorisation of novel foods permitted for use in food supplements, including conditions of use.	
Regulation (EC) No 178/2002 [26] on general food law	• Food safety requirements. • Responsibilities and obligations of economic operators.	
Regulation (EC) No 852/2004 [27] on food hygiene	• Rules for hygienic production based on the principles of HACCP.	
Regulation (EC) No 1333/2008 [28] on food additives	• Authorised food additives and conditions of use.	
Regulation (EC) No 1334/2008 [29] on flavourings and certain food ingredients with flavouring properties for use in and on foods	• Authorised flavouring substances and conditions for the presence of certain substances in food.	
Regulation (EC) No 1881/2006 [30] on contaminants	• Maximum levels of contaminants.	
Directive 2009/32/EC [31] on extraction solvents	• Permitted extraction solvents and residue levels.	
Regulation (EC) No 396/2005 [32] on pesticide residues	• Maximum residue levels.	
Directive 1999/2/EC [33] on foods and food ingredients treated with ionising radiation	• Permitted ingredients that may be treated with ionising radiation are specified in Directive 1999/3/EC [34]	• Food and food ingredients that may be treated with ionizing radiation at national level are included in a specific list [35]

20 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02002L0046-20170726&qid=1610972331033
21 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R1924-20141213&qid=1610972416913
22 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R1925-20190515&qid=1610972374478
23 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02011R1169-20180101&qid=1610972454734
24 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02015R2283-20210327&qid=1610972490726
25 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02017R2470-20200827&qid=1610972521752
26 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02002R0178-20190726&qid=1610972619718
27 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02004R0852-20090420&qid=1610972646700
28 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02008R1333-20201223&qid=1610972689416
29 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02008R1334-20201203&qid=1614871156112
30 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R1881-20201014&qid=1610972721710
31 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009L0032-20161109&qid=1610972766566
32 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02005R0396-20201216&qid=1610972811177
33 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A01999L0002-20081211&qid=1610972845661
34 https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:31999L0003
35 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52009XC1124(02)&from=EN

Food supplements must comply with all EU applicable legislation as presented in the above table. Any issue related to the application of these harmonised EU rules cannot be considered as a breach of Mutual Recognition.

In addition, for food supplements specifically, the following elements have been harmonised by Directive 2002/46/EC:

- The vitamins and minerals that can be added to food supplements;
- The nutritional substances that can be used as sources of vitamins and minerals in food supplements, including the purity criteria wherever established by EU law;
- The labelling requirements that are specific for food supplements.

Any issue that relates to the application of these elements cannot be considered as a breach of Mutual Recognition.

The following aspects have not been harmonised and are therefore subject to the principle of Mutual Recognition:

- The maximum amounts of vitamins and minerals present in food supplements;
- The substances other than vitamins and minerals, e.g. amino-acids, enzymes, plants and plant preparations, micro-organisms and other substances such as taurine, lutein, CoEnz Q10, lycopene, glucosamine, chondroitin, … that food supplements may contain;
- Conditions of use applying to food supplement ingredients (e.g. maximum levels, advisory statements, etc);
- Additional labelling requirements, not covered by Regulation (EU) No 1169/2011 or Directive 2002/46/EC.

Non-compliance of composition and labelling of food supplements with national legislation in the Member State of destination is therefore in the majority of cases subject to Mutual Recognition.

2. The food supplement must have been legally marketed in at least one Member State

The principle:

Mutual Recognition can only apply if the food supplement is legally marketed in another Member State. [36]

It is not sufficient that the product is only produced in conformity with national legislation in that Member State; it must be on the market.

For products to be considered to be lawfully marketed in another Member State, two conditions must be met: The product must

i) comply with the relevant rules applicable in that Member State, and

ii) be made available to end users in that Member State.

36 Or Liechtenstein, Iceland and Norway.

Regulation (EU) 2019/515 defines both concepts:

- **'lawfully marketed in another Member State'** means that goods or goods of that type 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.
- **'making available on the market'** means 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.

A food supplement is therefore considered to be lawfully marketed:

- when it fully complies with the legislation in place in a Member State. Where no national legislation is in place, the product is considered lawfully marketed per default. The food supplement must obviously comply with all applicable EU legislation also.
- In addition, the economic operator must have proof that the product is supplied to end users in that Member State.

  In this respect, the term "End User" covers both consumer (i.e. outside of any trade, business, craft or profession) and professionals (i.e in the course of their industrial or professional activities).

It is essential that the product is made available to end users in the Member State. There is no minimum duration of such marketing, nor are specific volumes or distribution channels specified.

The concept of "making available on the market" in a Member State does not only cover the presence of products in brick and mortar shops but also offering products to end consumers via direct sales and online web shops.

The Member State in which the product is lawfully marketed does not need to be the Member State the product originates from. Any Member State is suitable. The product must however be in compliance with the national rules of the same Member State in which it is made available to the end users. [37]

Mutual Recognition does not immediately apply to products imported from thirds countries into the EU. However, as soon as such products are released for free circulation and lawfully marketed in a Member State, Mutual Recognition applies.

Detailed information about the concept of lawfully marketed is available in the Commission services guidance on the concept of lawfully marketed. [38]

To prove lawful marketing in a Member States, Regulation (EU) 2019/515 has established a voluntary self-declaration possibility called the Mutual Recognition Declaration.

Justification to prove lawful marketing can be provided by means of any documents (e.g. invoices) that contains unambiguous data that identifies all of the following:

- the products;
- the suppliers, customers or end-users (personal data can be hidden to protect privacy);
- the date.

This also applies to online sales.

37 One notable exception is for goods lawfully marketed in Iceland, Liechtenstein and Norway. Such goods must originate from the same country or from an EU Member State. The UK is excluded from the principle of Mutual Recognition (see Q&A section for more details)

38 https://eur-lex.europa.eu/resource.html?uri=cellar:535184d6-08b9-11e3-a352-01aa75ed71a1.0004.01/DOC_1&format=PDF

3. The food supplement must have been notified in the Member State of destination if such a requirement exists

The principle:

Food supplements can only benefit from Mutual Recognition if they have complied with any procedural requirements applicable to the marketing of food supplements.

This means that food supplements must be notified both in the Member State of lawful marketing and the Member State of destination, if such notification is required.

The Food Supplements Directive 2002/46/EC allows Member States to implement a notification procedure to facilitate efficient monitoring of food supplements. This requires the person placing the product on the market to notify the competent authority of that placing on the market by forwarding it a model of the label used for the product.

All Member States, except Austria, the Netherlands, Slovenia and Sweden have implemented such a notification procedure.

In principle notification by means of the product label, is sufficient. However, many Member States have imposed more detailed requirements and request more information. This is possible, provided the notification system is not applied as a pre-market authorisation procedure and products can be marketed as soon as they have been notified.

Member States are not obliged to reply to a notification, unless such obligation is specified in national law. If a Member State fails to reply, waiting for such a reply cannot be considered as a refusal for placing the product on the market and thus, as a breach of Mutual Recognition.

Also requests for further information by the authority is not a denial of Mutual Recognition.

In some Member States, a prior market authorisation procedure exist for economic operators to follow allowing to request derogations from applicable national legislation, e.g. to obtain authorisation of a higher level of vitamins and minerals than permitted or to enable the use of an ingredient that is not permitted.

The existence of such a procedure in itself restricts the free movement of goods. In order to be justified with regard to the fundamental principle of the free movement of goods, such a procedure has to pursue a public interest objective recognised by Union law (e.g. the protection of health), and it has to be proportionate and non-discriminatory. It must be accessible and capable of being completed within a reasonable time. The CJEU has ruled that an application to have a product excluded from a prohibition may be refused by the competent authorities only on the basis of a full assessment of the risk posed to public health by the product, established on the basis of the most reliable scientific data available and the most recent results of international research. If the procedure results in a refusal, the refusal must be open to challenge before the courts. [39]

39 Judgment of the Court of 5 February 2004 in Case C-24/00 - Commission v France EU:C:2004:70, paragraphs 26, 27 and 36.

In the area of Food Supplements, such pre-market authorisation procedures are in principle not foreseen under Directive 2002/46/EC. The compliance of such a procedure with Union law is to be assessed in the light of the considerations set out in the case-law of the CJEU as described above and thus does not fall under the Mutual Recognition Regulation.

The requirement to follow such a prior authorisation procedure before the product may be placed on the market is not an administrative decision under Regulation (EU) 2019/515. Nevertheless any administrative decision to reject the placing of the product as a result of such a procedure falls under the provisions of Mutual Recognition.

It follows that where such pre-market authorisation procedure exist in national legislation for food supplements, it must be followed. If on the basis of such procedure, market access would be denied, this would fall under Mutual Recognition and can be addressed under the problem-solving procedure of Regulation (EU) 2019/515.

If the outcome of the procedure is not completed within the established deadlines or, in the absence of such, within a reasonable timeframe, or if for other reasons no administrative decision is taken, the problem solving procedure of Regulation (EU) 2019/515 cannot be initiated. The case can nevertheless be submitted in the normal SOLVIT procedure.

4. The refusal of Mutual Recognition by a Member State must be subject to an administrative decision

The principle:

Only an explicit prohibition, imposed restriction or obligation to be fulfilled before the product can be placed on the market, based on a technical rule, is grounds to start the Mutual Recognition problem solving process.

The general rule is that any product lawfully marketed in a Member State can be placed on the market of another Member State under the principle of Mutual Recognition. Compliance with national applicable provisions in the other Member State is then not required.

Only if access would be denied or restricted by an administrative decision based on non-compliance with the national rules, can the problem-solving procedure of Regulation (EU) 2019/515 be applied.

The concept of “Administrative Decision” is broad as it encompasses any administrative step that is based on a national technical rule and that has the same or substantially the same legal effect to restrict or deny market access in the Member State of destination. Such ‘administrative steps’ do therefore not need to be called ‘decision’.

Also the concept of "Technical Rule" is broad as it covers 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 Union 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:

   i. 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;

   ii. 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, such as 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.

Food supplements need to be notified in most Member States at the latest the moment the product is placed on the market. Waiting for a reply is therefore not a necessary prerequisite for placing the product on the market and failure from the Member State to reply to a notification cannot be considered as a denial of marketing.

In case a Member State informs the economic operator that it is assessing the product or requests more information, also such communication is not an administrative decision denying market access, unless the communication explicitly indicates that the product cannot be placed on the market. Where an authority is assessing the products before deciding whether to restrict or deny market access, that authority cannot take decisions to suspend market access (except where rapid intervention is required to prevent harm to the safety or health of consumers).

If the authority refers to a procedure to be completed, that is described in law, this must be followed before any administrative decision is taken that can serve as basis for a Mutual Recognition case.

Decisions of national courts or tribunals are also not covered by Regulation (EU) 2019/515 and neither are measures taken for safety reasons under the provisions of the General Food Law Regulation (EC) No 178/2002.

5. The technical rule must have been notified in TRIS

The principle:

A prohibition, restriction or request for further actions cannot be enforced if the technical rule on which they are based, has not been notified to the Commission in the TRIS system under Directive (EU) 2015/1535 [40]

Specific provisions of food supplements that have so far not been harmonised but are governed by national legislation and/or national technical rules (e.g. lists of ingredients permitted or prohibited in food supplements, whether in law or applied as administrative practice) must be notified to the EC in accordance with Directive (EU) 2015/1535 (previously Directive 98/34/EC c.q. Directive 83/189/EEC).

A breach of the obligation to notify such technical rules renders these rules inapplicable, so that they are unenforceable against individuals. [41] Therefore, such national legislation or practice can only be applied if the Member State has notified this in accordance with Directive (EU) 2015/1535.

All notifications are listed in the Technical Regulation Information System (TRIS) database. On the TRIS website of the Commission, it can therefore be checked if the national technical rule applicable to the case has been notified in TRIS. [42]

It must be noted that the fact that a technical regulation has been notified in TRIS does not mean that its application is guaranteed to be compatible with EU law. It can certainly be the basis for Mutual Recognition cases.

40 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32015L1535&qid=1610989480375
41 Judgement of 30 April 1996 in Case C-194/94 - CIA Security v Signalson. EU:C:1996:172, Paragraph 32.
42 https://ec.europa.eu/growth/tools-databases/tris/en/

4. The Mutual Recognition Declaration

Since the evidence required to demonstrate that goods are lawfully marketed in another Member State varies between Member States, Regulation (EU) 2019/515 has created the possibility for economic operators to draw up a **self-declaration** that provides authorities with all necessary information on the goods and on their compliance with the rules applicable in the Member State in which the product is lawfully marketed. This is an easy tool for economic operators to demonstrate that the goods they want to place on the market are lawfully marketed in another Member State.

The drawing up of this Mutual Recognition Declaration is voluntary.

If an economic operator choses not to draw up a Mutual Recognition Declaration, this does not make Mutual Recognition optional for the authorities. Authorities have the obligation to contact and inform an economic operator without delay in case they intend to assess goods subject to Mutual Recognition, e.g. to establish whether the goods or goods of that type are lawfully marketed in another Member State. They must identify the goods subject to this assessment and specify the technical rules that are applicable and/or any prior authorisation that applies. They must also inform the economic operator of the possibility of supplying a Mutual Recognition Declaration.

If a Mutual Recognition Declaration is not supplied to the authority of the Member State of destination, the authority may request the economic operator to provide documentation and information about the characteristics of the goods or type of goods in question and the lawful marketing of these goods in another Member State, to properly assess if the product is lawfully marketed in another Member State.

The Mutual Recognition Declaration can be completed by any economic operator, be it the **producer, importer (for goods imported into the EU from Third Countries) or distributor (for goods placed on the market within the EU)**.

In this respect, producer is defined as:

(a) any natural or legal person who manufactures goods or has goods designed or manufactured, or who produces goods which were not the result of a manufacturing process, including agricultural products, and markets them under that person's name or trademark

(b) any natural or legal person who modifies goods already lawfully marketed in a Member State in a way that might affect compliance with the relevant rules applicable in that Member State, or

(c) any other natural or legal person who, by putting its name, trademark or other distinguishing feature on goods or on the documents that accompany those goods, presents itself as the producer of those goods.

The term 'producer' is therefore broader than the 'manufacturer', as the manufacturer is usually not aware of the lawful marketing of the product. Any economic operator, who places a food on the market under his name (and thus is the 'product owner') is covered by this definition.

For food supplements, the economic operator who is responsible for the placing on the market of the product in the other Member State is best placed to complete the declaration, as he is in possession of the necessary information about the product, its composition and its lawful marketing in the Member States, that is required for the Mutual Recognition Declaration. The producer can however also mandate an **authorised representative** to draw up such declarations on his behalf and under his responsibility. This is any natural or legal person established within the EU who has received a written mandate from a producer to act on that producer's behalf with regard to the making available of goods on the market in question.

The **structure and information** the declaration should contain are specified in Parts I and II of the Annex of Regulation (EU) 2019/515. This is reproduced in the Annex to this guideline. Part I relates specifically to information about the product (which usually is in possession of the producer (or its authorised representative)), while the information in Part II relates to the lawful marketing of the product (which may be better known by the importer or by the distributor). For food supplements, the information to be included in both parts is usually in possession of the economic operator under whose name the product is marketed, which enables him to complete both parts.

The Mutual Recognition Declaration must be drawn up in **one of the official languages** of the EU but must be translated into a language required by the Member State of destination. The template is available in all official languages of the EU on the website of the EC. [43]

Economic operators who sign the Mutual Recognition Declaration are **responsible for the content and accuracy** of the information and liable in accordance with national laws.

They must ensure that the Mutual Recognition Declaration is **kept up to date** at all times, based on any changes in the information that they are aware of. The Mutual Recognition Declaration should always contain up-to-date, accurate and complete information on the product. This also means that if the national legislation or technical rules in the Member State in which the product is lawfully marketed change, the conformity with the new rules must be checked and the product, where necessary, adapted.

The Mutual Recognition Declaration may be supplied to the competent authority of the Member State of destination for the purpose of an assessment, either **in paper form or by electronic means**. It may also be made available **online** in accordance with the requirements of the Member State of destination. When this is the case, the product or type of products to which the Mutual Recognition Declaration applies must be easily identifiable and the technical means used must ensure easy navigation and be monitored to ensure the availability of, and access to, the Mutual Recognition Declaration.

More information on this declaration can be found on the website of the EC. [44]

Although this self-declaration must be accepted by the Member States, they of course have the right to investigate the correctness of the declaration.

43 https://ec.europa.eu/docsroom/documents/40922

44 https://europa.eu/youreurope/business/product-requirements/compliance/declaration-mutual-recognition/index_en.htm

In that respect the economic operator should provide evidence such as

- product invoices specifying the products, customer or end user and date
- product labels
- catalogue with evidence of a date
- sale or tax records
- registrations, licences, notifications to/from the authorities
- certifications
- extracts from public records, etc. to demonstrate the actual marketing of the product in another Member State

Also in the case of direct sales and products offered for sale via online platforms, evidence that the product is made available to consumers in the first Member State that serves as a reference for Mutual Recognition, is required. Economic operators can demonstrate such lawful marketing by providing evidence such as:

- invoices (where the personal data of the consumer could be deleted before its submission to the authorities to respect privacy rules, but showing the city or place of delivery).
- proof that the web shop is operating in the Member State of origin (for example the webadress. country code).
- a screen print of a page showing that
  - the product is available to end users in that Member State (for example, using the search option for the specific product and making a screen shot).
  - the website displays information relating to the Member State, e.g. information in the language of the Member State, delivery options/costs to that Member State).
- demonstration that the product is notified as required in that Member State.

5. The Mutual Recognition Procedure

Step 1 – Assessment by a national authority

The principle:

A Member State may assess the product and request the Mutual Recognition Declaration (or in its absence equivalent information to check the lawful marketing). It must inform the economic operator of this assessment.

During this assessment the product may be placed on the market.

If it reaches an administrative decision denying Mutual Recognition, the authority must inform the economic operator, the EC and the other Member States of its decisions that must be sufficiently detailed and reasoned.

Food supplements require notification in most Member States at the latest at the moment they are placed on the market.

Although not legally required, it is recommended that an economic operator placing the product on the market be aware of the national legislation that is applicable to the products to assess the probability of a challenge by a national authority. If not available, such information can be obtained from a Product Contact Point.

Following notification or in the course of official controls, the national authority can assess the product. In such case, the Member State has the obligation to contact the economic operator without delay and inform the economic operator of the assessment and the applicable technical rule or prior authorisation procedure. The authority must also inform the economic operator of the possibility of supplying a Mutual Recognition Declaration.

If no prior authorisation procedure is applicable, the economic operator is allowed to make the food supplement available on the market during this assessment until an administrative decision restricting or denying market access for the products is received. In case a prior authorisation procedure applies, this must be followed first.

If the economic operator submits the Mutual Recognition Declaration, together with supporting evidence necessary to verify the information contained in it, Member States are obliged to accept this as sufficient to demonstrate that the products are lawfully marketed in another Member State. The authorities cannot require any other information or documentation for the purpose of demonstrating that the goods are lawfully marketed in another Member State.

If the economic operator does not submit a Mutual Recognition Declaration, the authority may obviously request documentation and information that is necessary for that assessment. The economic operator must at least get 15 working days to submit this information.

The authority must notify the economic operator of its administrative decision without delay and before it takes effect. It must also notify the EC and the other Member States via the ICSMS system [45] (or, as the case may be the RASFF (Rapid Alert System for Food and Feed)) no later than 20 working days after it took the decision.

The administrative decision must specify the reasons for the decision in a manner that is sufficiently detailed **and reasoned** to facilitate an assessment of its compatibility with the principle of Mutual Recognition and with the requirements of Regulation (EU) 2019/515.

This means that the decision must at least contain the following information:

- The **national technical rule** on which the administrative decision is based;
- The **legitimate public interest grounds** justifying the application of the national technical rule on which the administrative decision is based;
- The **technical or scientific evidence** that the competent authority of the Member State of destination considered, including, where applicable, any relevant changes in the state of the art that have occurred since the national technical rule came into force;
- A **summary of the arguments** put forward by the economic operator concerned that are relevant for the assessment, if any;
- The evidence demonstrating that the administrative decision is **appropriate** for the purpose of achieving the objective pursued and that the administrative decision **does not go beyond what is necessary** in order to attain that objective;
- The **remedies** available under the national law of the Member State of destination and the time limits applicable to those remedies;
- A reference to the possibility for economic operators to use **SOLVIT** and the problem-solving procedure.

During this assessment process, and provided no pre-market authorisation process is in place, the product can remain on the market until the administrative decision is notified.

Member States may temporarily suspend market access **only** if under normal or reasonably foreseeable conditions of use, the goods pose a **serious risk** to the safety or health of persons or to the environment, including one where the effects are not immediate, which requires rapid intervention by the competent authority; or when 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. For food and food supplements the conditions for this are specified in the General Food Law Regulation (EC) No 178/2002.

The burden of proof to demonstrate that the restriction is necessary and proportionate and that the objective of the protection of health pursued cannot be achieved by measures that are less restrictive of trade lies with the Member State authority.

Regulation (EU) 2019/515 does not describe the procedure for the discussions between the authority and the economic operator during this assessment process and where a decision is taken to deny Mutual Recognition. Such a procedure with deadlines was foreseen under the previous Regulation, but experience showed it was not applied.

45 Commission Implementing Regulation (EU) 2020/1668 of 10 November 2020 specifying the details and functionalities of the information and communication system to be used for the purposes 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. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32020R1668&qid=1615279383948

Nevertheless, the administrative decision must provide a summary of the arguments put forward by the economic operator, which means that the economic operator must have had an opportunity to provide information to address the reasons put forward by the authority to deny Mutual Recognition.

It is therefore important for the economic operator to remain in contact with the authority at the moment it is informed that the product is being assessed. It is recommended that the economic operator responds to the communication that the product is being assessed by requesting to be informed of the reasons for the potential denial of Mutual Recognition or provides information that addresses the relevance of the technical rule under which the assessment takes place, which must be specified in that communication by the authority.

Since food supplements require notification in most Member States, authorities can assess the product at the moment of notification. In that case they also need to inform the economic operator that the product is being assessed. They cannot take an administrative decision to deny Mutual Recognition solely based on the notification as the requirements of Regulation (EU) 2019/515 would in that case not have been respected.

Step 2 – The problem-solving procedure

The principle:

An economic operator may submit the administrative decision to SOLVIT.

The SOLVIT Centre can ask the EC for an opinion on the case, which must be considered.

SOLVIT [46] is a service provided by the national administration in each EU country and in Iceland, Liechtenstein and Norway that assists citizens and businesses whose rights are breached by public authorities in another EU Member State. SOLVIT is free of charge and aims to solve issues within 10 weeks after a case is accepted.

The principles governing the functioning of SOLVIT are set out in Commission Recommendation 2013/461 EU. [47]

SOLVIT already assisted economic operators in cases of Mutual Recognition, but with Regulation (EU) 2019/515 its role has become far more important.

A SOLVIT Centre case involves two centres: The local SOLVIT centre (called the Home Centre) and the SOLVIT centre in the country where the problem occurred (called the Lead Centre).

The contact details of the SOLVIT Centres can be found on the EC website. [48]

Any administrative decision that denies Mutual Recognition can be submitted to the local SOLVIT Centre, that will help solve the issue by contacting the respective authorities.

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

46 https://ec.europa.eu/solvit/what-is-solvit/index_en.htm
47 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32013H0461&qid=1610989872239
48 https://ec.europa.eu/solvit/contact/

The Home Centre is responsible for preparing and making a legal assessment of the case before submitting it to the SOLVIT centre of the authority about which a complaint has been made (Lead Centre).

During this process, either the Home or Lead Centre may request the EC to give an opinion in order to assist in solving the case, having provided the EC with all relevant documents relating to the administrative decision.

The EC will assess whether the administrative decision is compatible with the principle of Mutual Recognition and with the requirements of Regulation (EU) 2019/515. The EC may ask for additional information via the SOLVIT Centres.

The assessment must be completed within 45 working days of receipt of the request and an opinion issued. Where appropriate, the EC's opinion must identify any concerns that should be addressed in the SOLVIT case or must make recommendations to assist in solving the case.

The EC's opinion will be communicated through the SOLVIT Centre to the economic operator and to the relevant authorities and notified by the EC to all Member States.

The opinion must be taken into account during the SOLVIT procedure.

The economic operator may also make use of the opinion and make it available to any relevant third parties.

It should be noted that economic operators can also submit cases on free movement of goods that do not fulfil the criteria of the Mutual Recognition Regulation to SOLVIT (e.g. in cases where there is no administrative decision or lack of reply by the national authority). These cases will be handled under the normal SOLVIT procedure, the main difference being that they cannot benefit from an EC opinion as provided for in the problem solving procedure under Regulation (EU) 2019/515.

6. The role of the Product Contact Points

Regulation (EC) No 764/2008 had established a network of Product Contact Points, which remain and are empowered by Regulation (EU) 2019/515. Member States must ensure that Product Contact Points deliver their services in accordance with Regulation (EU) 2018/1724. [49]

Product Contact Points are a useful reference point for economic operators.

Product Contact Points should provide online the following information:

- Information on the principle of Mutual Recognition and the application of Regulation (EU) 2019/515 on the territory of their Member State, including information on the procedure used by the authorities to assess products placed on the market;
- The contact details of the competent authorities within that 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;
- 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 of Regulation (EU) 2019/515.

Product Contact Points must also provide, at the request of an economic operator or a competent authority of another Member State, any useful information, such as electronic copies of, or online access to, the national technical rules and national administrative procedures applicable to specific goods or goods of a specific type in the territory in which the Product Contact Point is established or information on whether those goods or goods of that type are subject to prior authorisation under national law.

Product Contact Points have the obligation to respond within 15 working days of receiving any request. This service is free of charge.

The details of the Product Contact Points are listed on the Commission's website. [50]

49 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32018R1724&qid=1610989985428

50 https://ec.europa.eu/growth/single-market/goods/free-movement-sectors/mutual-recognition/contacts-list_en

7. Frequently Asked Questions

Q. **A food supplement is lawfully marketed in an EU Member State. It is placed on the market in another Member State, but with a different label. Does Mutual Recognition apply?**

A. Yes, Mutual Recognition applies to the product. The labelling requirements are harmonised at EU level and Article 15 of Regulation (EU) No 1169/2011 requires that food information shall appear in a language easily understood by the consumers of the Member States where a food is marketed.

Any non-harmonised aspect of the composition, as well as non-harmonised additional labelling requirements fall under the scope of Mutual Recognition.

Mutual Recognition does not only apply to a specific product but also to products "of a given type". The product therefore does not need to have the same label or be sold under the same name for Mutual Recognition to apply. This means that:

- the label can be in a different language (as required by Regulation (EU) No 1169/2011).
- the label can have a different design in terms of colour and print, e.g. to respond to different consumer expectations in the Member State of destination.
- the label can provide information that is different from the original label, provided the information is in compliance with harmonised EU legislation or, when not harmonised, with national legislation in the Member State in which the product is lawfully marketed.
- the product can be presented in a different pack size, provided the composition and other aspects of the product remain unchanged.
- the product can even be marketed under a different name.

In all the above cases, Mutual Recognition applies when it can be demonstrated that the product is the same in terms of composition and other non-harmonised aspects as the product that is lawfully marketed in another Member State.

The economic operator should therefore have information available to show that the products are "of the same type", despite the differing label, pack size or name and provide this together with the Mutual Recognition Declaration. This can include pictures of the packaging of both products, where it can be shown that the composition is the same by means of the list of ingredients and the nutritional labelling.

Q. **A food supplement is lawfully marketed in an EU Member State. It is however not placed on the market by the same business operator who wants to market the same product in another Member State. The product has the same composition but will be marketed under another name and with a different label. Can Mutual Recognition apply?**

A. Yes, Mutual Recognition can apply to the product. Regulation (EU) 2019/515 does not cover only "goods" but also "goods of a given type". If the business operator can demonstrate that the product is the same in terms of product composition and ingredients as the product that is lawfully marketed in the other Member State, Mutual Recognition applies. The evidence to demonstrate this must be available and provided together with the Mutual Recognition Declaration.

Q. **A food supplement is lawfully marketed in a Member State in which there are no specific rules applicable to the product and where there is no notification requirement. The product is placed on the market in another Member States (with or without a notification obligation). The product does not comply with the detailed national legislation in the Member State of destination. Does Mutual Recognition apply?**

A. Yes, Mutual Recognition applies, provided that the product is duly notified, if applicable, in accordance with the procedure of the Member State of destination. Since no specific national legislation in the original Member State in which the product is lawfully marketed exists, the economic operator only needs to prove that the product is lawfully marketed in that Member State. In case during the notification, the national authorities of the member State of destination take an administrative decision to deny Mutual Recognition, the procedures of Regulation (EU) 2019/515 apply.

Q. **A food supplements is lawfully marketed in an EU Member State. The level of certain vitamins and minerals is however exceeding the maximum levels set by national legislation in the Member State of destination. Upon notification, the authorities communicate in writing that they refuse the marketing of the product based on a scientific opinion by their national scientific advisory board. They indicate that it is possible to appeal to this decision, either through an administrative process within the relevant department or by a procedure via the State Council. Is this an acceptable ground for denying Mutual Recognition?**

A. This issue falls within the scope of Mutual Recognition and the problem solving procedure of Regulation (EU) 2019/515 can be followed.

The aspect of maximum levels of vitamins and minerals is not harmonised. The food supplement was duly notified. The decision in writing that the marketing of the product is refused is an administrative decision, based on a technical rule (the national Food Supplements Decree). This therefore qualifies as refusal of Mutual Recognition and the problem-solving mechanism of Regulation (EU) 2019/515 can be applied.

The reason brought forward by the authorities to refuse the marketing of the product is based on the protection of health and life of humans. This is a justified ground under Article 36 TFEU. The levels included in the Member State's legislation are based on a scientific opinion. It is noted that this is a national opinion only and is not legally binding.

Whereas it might be appropriate to first appeal through the administrative process, this is not a legal obligation. It is nevertheless a possibility to bring justification arguments on the table of the authorities in view of accepting the product which is lawfully marketed in another Member State. It can also be part of the problem-solving when initiated via SOLVIT.

Such arguments could include a reference to the legislation in the Member State of origin and to the scientific opinions underlying this legislation (if any); references to other scientific opinions[51]; published or proprietary studies and research; etc. An analysis of the national scientific opinion can also be helpful to conclude to what extent the risks highlighted would be relevant or present for the product under consideration and if the decision to deny Mutual Recognition would be proportionate.[52]

A formal request for a derogation from the maximum levels laid down in the legislation could also be submitted.[53]

If help is sought from the SOLVIT Centre under the problem-solving procedure of Regulation (EU) 2019/515, it will be up to the authorities to justify the necessity and proportionality of the maximum levels laid down in their legislation and to show that for the product under consideration, the objective of protection of health pursued cannot be achieved by measures that are less restrictive of trade.

51 Judgment of the Court of 27 April 2017 in Case C-672/15 - Noria Distribution SARL. EU:C:2017:310. The CJEU judged that maximum levels cannot be based solely on national scientific opinions, when recent international scientific opinions concluding in favour of the possibility of setting higher limits are also available.

52 Judgment of the Court of 27 April 2017 in Case C-672/15 - Noria Distribution SARL. EU:C:2017:310. The CJEU judged that maximum levels must be based on a comprehensive scientific assessment of the risks for public health, based not on general or hypothetical considerations, but on relevant scientific data.

53 Judgment of the Court of 27 April 2017 in Case C-672/15 - Noria Distribution SARL. EU:C:2017:310. The CJEU judged that national legislation that establishes maximum levels for vitamins and minerals must be accompanied by a procedure for the placing on the market of food supplements whose content in nutrients exceeds the maximum daily doses set by that legislation and which are lawfully manufactured or marketed in another Member state.

Q. A food supplement lawfully marketed in a Member State is refused access to the market of another Member State because one of its ingredients is regarded as novel food. Can Mutual Recognition apply?

A. Mutual recognition does not apply since novel foods legislation is harmonised.

Regulation (EU) 2015/2283 defines novel food as any food or food ingredient that was not used to a significant extent in or as food in the EU before 15 May 1997 and belongs to a number of categories. Such foods require prior market authorisation.

Economic operators have the obligation to verify whether any food ingredient they want to use would fall under the scope of Regulation (EU) 2015/2283. If they are unsure, they must ask a competent authority. The outcome of such discussions are published on the EC website. [54]

Under Article 5, the EC also has the possibility to decide whether or not a particular food falls within the definition of novel food.

In addition, the Novel Food Catalogue provides information on the status of a number of food and food ingredients, based on the outcome of discussions at EU level. [55]

Only non-novel foods and authorised novel foods are permitted as ingredients in food supplements. Authorised novel foods are included in the Union List of Novel Foods established by Implementing Regulation (EU) 2017/2470.

Issues relating to the novel food status are therefore covered by this harmonised novel food legislation and cannot be subject to Mutual Recognition.

54 https://ec.europa.eu/food/safety/novel_food/consultation-process_en

55 https://ec.europa.eu/food/safety/novel_food/catalogue_en

Q. A food is lawfully marketed in one Member State as Food for Special Medical Purposes (FSMP). During notification, the product is denied access to the market in another Member State because the Member State argues that the food is incorrectly classified as FSMP and should be marketed as food supplement. Can Mutual Recognition apply?

A. Mutual recognition does not apply since both definitions of food supplement and FSMP are subject to harmonised legislation.

The definition of food supplement is included in Directive 2002/46/EC:

'food supplements' means foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities.

Food supplements are therefore concentrated sources of nutrients or other substances marketed in dose form and designed to be taken in small unit quantities. The quantity, dose and unit form will be determining to decide on the status and differentiation with other foods, such as FSMP.

The definition of FSMP is laid down in Regulation (EU) No 609/2013[56], and further requirements in Regulation (EU) 2016/128[57]. This is therefore also fully harmonised. In addition, the EC has published guidelines on how to assess the correct positioning of a food as FSMP (Commission Notice on the classification of Food for Special Medical Purposes - C/2017/7716).[58]

Disputes as to the status of a product as food supplement or FSMP are therefore not subject to Mutual Recognition.

56 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02013R0609-20170711&qid=1610990354487
57 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02016R0128-20200514&qid=1610990394478
58 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52017XC1125(01)&from=EN

Q. A food supplement intended for infants and young children is lawfully sold in one Member State. When notified to another Member State the product is not accepted. The reason given by the authorities is that a food supplement cannot be intended to children younger than 3 years of age and should be covered by another food category i.e. Food for Specific Groups. Can Mutual Recognition apply?

A. Mutual Recognition can apply.

The refusal during the notification of such a food supplement, lawfully marketed in another Member State can be considered an administrative decision. The effect of that administrative decision is a restriction of market access in the Member State of destination, since it would require changes to the product (e.g. composition and/or labelling).

Such decision cannot be justified on the basis of EU applicable legislation:

- Food Supplements are defined in by Directive 2002/46/EC. This Directive does not restrict the use of food supplements to consumers over the age of 3 years.
- Foods for Specific Group legislation, Regulation (EU) No 609/2013, only covers compositional and information requirements for the following categories of food:
  - infant formula and follow-on formula;
  - processed cereal-based food and baby food;
  - food for special medical purposes;
  - total diet replacement for weight control.

  These products are defined in a way that cannot be considered to cover the form or type of food supplement.

A Member State that refuses a food supplement intended for use in children below the age of 3 years because it considers this as belonging to a category other than food supplements as defined in Directive 2002/46/EC, would not be applying this legislation correctly. The Member State would need to specify the applicable national technical rule under which this decision is taken and justify the proportionality and necessity of this decision.

Q. A food supplement is lawfully marketed in one Member State with health claims that are on hold. The product is denied access to the market in another Member State because of these health claims. Can Mutual Recognition apply?

A. Mutual Recognition can apply.

The use of nutrition and health claims made on foods, including food supplements, is harmonised by Regulation (EC) No 1924/2006. Only health claims that have been authorised can be made on foods.

Nevertheless, a number of health claims remain on hold. For these health claims no decisions have been taken yet, since the assessments by EFSA have been put on hold.

These claims can continue to be used on the market under the responsibility of the food business operator provided they comply with the general principles of Regulation (EC) No 1924/2006 and existing national provisions applicable to them.[59]

This means that for the on hold health claims themselves, since they can be made subject to national provisions, Mutual Recognition can apply, but not for the aspects that have been harmonised (e.g. relating to disputes about the general conditions for the use of health claims or the labelling requirements imposed by Regulation (EC) No 1924/2006 or Regulation (EU) No 1169/2011).

The reason for the denial of Mutual Recognition will therefore need to be closely assessed to ensure this does not cover a harmonised aspect of Regulation (EC) No 1924/2006.

The use of authorised health claims and differences in appreciation or interpretation between the Member States as to the wording of such claims fall outside the scope of Mutual Recognition.

All harmonised authorised and rejected health claims can be found on the website of the EC in the so-called Register of Health Claims.[60] Also the health claims that have been put on hold can be found on this website.[61]

The use of reduction of disease risk claims is also harmonised. A food supplement using an authorised reduction of disease risk claim should not be prevented from being marketed in another Member State or be considered as a medicinal product because of that reason. Nevertheless, differences in application in this respect cannot be considered under Mutual Recognition.

59 https://ec.europa.eu/commission/presscorner/detail/en/MEMO_11_868
60 https://ec.europa.eu/food/safety/labelling_nutrition/claims/register/public/?event=register.home
61 https://ec.europa.eu/food/safety/labelling_nutrition/claims/register/resources/docs/claims_pending.pdf

Q. A food supplement is lawfully marketed in one Member State. The placing on the market in another Member State is denied. The Member State authority considers that an ingredient in the product is restricted to medicinal products only and that therefore the product cannot be placed on the market as food supplement. Does Mutual Recognition apply?

A. Mutual Recognition can apply.

A Member State can regard a certain product as medicinal product on its territory even though that product is placed on the market as food supplement in another Member State.[62] Nevertheless, in doing so authorities must respect the criteria put forward by the CJEU in its case law and any decision must respect the principles of necessity and proportionality.

The reasons for which registration as medicinal product is requested are therefore of importance to decide if Mutual Recognition applies or not.

- One reason for which a product can be considered as medicinal product is the way in which it is presented. The CJEU has ruled that any product, presented as having properties for treating or preventing disease is to be regarded as falling under medicinal law. This is not only when the product is expressly 'indicated' or 'recommended' as such but also when any averagely well-informed consumer would gain the impression that the product is intended for the prevention or treatment of diseases.[63]

  This is because not only such statements are plainly prohibited under EU Food Information (Article 7.3 of Regulation (EU) No 1169/2011) and Food Supplements (Article 6.2 of Directive 2002/46/EC) law, but also because it is the aim of medicinal legislation to ensure that the attributed properties are present and where not, to refuse a medicinal licence.[64]

  In this case Mutual Recognition cannot apply, as this aspect is harmonised by EU legislation.

- Another reason to consider a product subject to medicinal legislation is because it may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions, by pharmacological, metabolic or immunologic means. The CJEU has ruled that this must be ascertained on the basis of a number of criteria and that any restriction based on this must comply with Articles 34-36 TFEU.

  In particular the following requirements apply:

  – Medicinal law can only be applied to products that satisfy equally well the conditions for classification as a foodstuff and the conditions for classification as a medicinal product.[65] Where a product comes clearly under the definition of other product categories, in particular food or food supplements the medicinal product legislation should not apply (Recital 7 of Directive 2004/27/EC).[66] Only in cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a "medicinal product" and within the definition of a product covered by other EU legislation the provisions of the Medicinal Product Directive apply (Article 2.2 of Directive 2004/27/EC).

62 Judgment 9 June 2005 in Joined Cases C-211/03, C-299/03 and C-316/03 to C-318/03 - Orthica, EU:C:2005:370. Paragraph 56
63 Judgment of the Court of 30 November 1983 in Case 227/82 - Van Bennekom, EU:C:1983:354. Paragraph 18
64 Judgment of the Court of 30 November 1983 in Case 227/82 - Van Bennekom, EU:C:1983:354. Paragraph 17
65 Judgment 9 June 2005 in Joined Cases C-211/03, C-299/03 and C-316/03 to C-318/03 - Orthica, EU:C:2005:370. Paragraph 45
66 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32004L0027&qid=1610992648537

– This assessment must be based on an assessment of all the product's characteristics. The CJEU clearly recognises that a physiological effect is not specific to medicinal products but is also among the criteria used for the definition of food supplements. In those circumstances, and in order to preserve the effectiveness of that criterion, it is not sufficient that the product has properties beneficial to health in general, but it must strictly speaking have the function of treating or preventing disease. [67]

  As a consequence, it rules that the Medicinal Product Directive 2001/83/EC [68] does not apply to a product in respect of which it has not been scientifically established that it is capable of restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action. [69]

  Products which, although they are capable of having an effect on bodily functions but do not significantly affect the metabolism and thus do not strictly modify the way in which it functions, cannot be considered as medicinal product. [70] This must be assessed on the basis of the pharmacological properties of a product. [71]

The use of other substances in food supplements is not yet harmonised. Any restrictions of the use of a certain ingredient in a food supplement that is lawfully marketed in another Member State is therefore subject to Mutual Recognition, and the reasons for any denial of Mutual Recognition, including considering the ingredient as requiring authorisation as medicinal product, must be assessed under Regulation (EU) 2019/515.

The CJEU considers that the requirement for a marketing authorisation as a medicinal product, is a measure having equivalent effect to a quantitative restriction on imports prohibited by Article 34 TFEU. In particular the means that the Member State choses must therefore be confined to what is actually necessary to ensure the safeguarding of public health; they must be proportional to the objective thus pursued, which could not have been attained by measures which are less restrictive of intra-Community trade.

Furthermore, since Article 34 TFEU provides an exception, to be interpreted strictly, to the rule of free movement of goods within the Community, it is for the national authorities which invoke it to show in each case, in the light of national nutritional habits and in the light of the results of international scientific research, that their rules are necessary to give effective protection to the interests referred to in that provision and, in particular, that the marketing of the products in question poses a real risk for public health. [72]

67 Judgment of the Court of 15 November 2007 in Case C-319/05 - European Commission vs Federal Republic of Germany, EU:C:2007:678. Paragraphs 63-64

68 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02001L0083-20190726&qid=1610992891778

69 Judgment of the Court of 15 January 2009 in Case C-140/07 - Hecht Pharma, EU:C:2009:5. Paragraphs 26 and29

70 Judgment of the Court of 15 November 2007 in Case C-319/05 - European Commission vs Federal Republic of Germany, EU:C:2007:678. Paragraph 60

71 Judgment 9 June 2005 in Joined Cases C-211/03, C-299/03 and C-316/03 to C-318/03 - Orthica, EU:C:2005:370. Paragraph 52

72 Judgment of the Court of 15 November 2007 in Case C-319/05 - European Commission vs Federal Republic of Germany, EU:C:2007:678. Paragraphs 87-88

Typical examples of substances restricted for use in food supplements include monacolin K, melatonin, lactulose and various botanical preparations. The fact that health claims have been authorised under Regulation (EC) No 1924/2006 confirms their effects in support of physiological functions. Authorisation of a health claim legally does not constitute an authorisation to the marketing of the substance on which the claim is made, nor is it a decision on whether the substance can be used in foodstuffs or a classification of a certain product as a foodstuff. Nevertheless, when used in compliance with the authorised conditions of use of the health claim, these substances should in principle be acceptable for use in food supplements in all Member States.

Therefore a decision to deny Mutual Recognition of such products can be submitted to the problem-solving procedure of Regulation (EU) 2019/515.

Q. **A food supplement is lawfully marketed in one Member State. It is placed on the market in another Member State and duly notified in accordance with national provisions. In that Member State, a notification number is assigned to that product. National legislation requires this number to be mentioned in all commercial documents relating to the notified product. It is common practice by trade that products that do not mention this number, are not accepted for sales.**

A product can therefore not be marketed in that Member State through regular distribution channels before this number is attributed or where this number is refused. Can refusal of this number be considered as an administrative decision that denies Mutual Recognition?

A. Yes. Regulation (EU) 2019/515 applies to all administrative decisions the "direct or indirect effect" of which is to restrict or deny market access in the Member State.

Given the legal obligation to mention this number in the commercial documents and the practice of trade not to accept for sales products that do not mention this number, the indirect effect of the refusal of such a number is the restriction or denial of market access.

CJEU case law confirms that 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. [73]

If the notification number is refused because of non-compliance with the national technical rule and not for other reasons, Such refusal must be considered as an administrative decision and can be subject to the problem-solving procedure of Regulation (EU) 2019/515.

73 Judgment of the Court of 8 September 2009 in case C-478/07 - Budějovický Budvar, národní podnik, EU:C:2003:618, paragraphs 81-82

Q. A food supplement is lawfully marketed in Northern Ireland. It is placed on the market in an EU Member State. Can Mutual Recognition apply?

A. No. Mutual Recognition cannot be applied. Products that are lawfully marketed in Northern Ireland cannot benefit from the principle of Mutual Recognition in the Member States of the EU.

Northern Ireland is part of the UK. The relationship between the EU and the UK as regards Norther Ireland is specified in the Protocol on Ireland/Northern Ireland of the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community.[74] The first subparagraph of Article 7(3) of that protocol states the following:

"By way of derogation from Article 13(1) of this Protocol and from Article 7 of the Withdrawal Agreement, in respect of the recognition in one Member State of technical regulations, assessments, registrations, certificates, approvals and authorisations issued or carried out by the authorities of another Member State, or by a body established in another Member State, references to Member States in provisions of Union law made applicable by this Protocol *shall not be read as including the United Kingdom in respect of Northern Ireland as regards technical regulations, assessments, registrations, certificates, approvals and authorisations issued or carried out by the authorities of the United Kingdom or by bodies established in the United Kingdom*."

The Notice to stakeholders regarding the Withdrawal of the United Kingdom and EU Rules in the field of industrial products[75] contains the following explanation concerning the first subparagraph of Article 7(3) of Protocol on Ireland/Northern Ireland:

"Consequently, in the non-harmonised area, the principle of Mutual Recognition in one Member State of goods lawfully marketed in another Member State pursuant to Articles 34 and 36 of the Treaty on the Functioning of the European Union will not apply in respect of goods lawfully marketed in Northern Ireland. This means that the lawful placing of a product on the market of Northern Ireland cannot be invoked when that product is placed on the market in the EU. However, the lawful marketing of a product in a Member State can be invoked when that product is placed on the market in Northern Ireland."

74 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A12020W/TXT#d1e32-102-1
75 https://ec.europa.eu/info/sites/info/files/notice_to_stakeholders_industrial_products.pdf

Annex: Mutual Recognition Declaration

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):

The European food supplement sector brings together many of the most innovative and dynamic companies in the food area, making a substantial contribution to Europe's public health goals.

Food Supplements Europe combines the unique expertise of associations and companies committed to building partnership with regulatory, scientific and consumer bodies to help shape the future regulatory and policy framework in this area and to ensure that consumers can benefit from safe and high quality products.

food supplements europe

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