

# Official Journal of the European Union

# C 100



English edition

## Information and Notices

Volume 64

23 March 2021

### Contents

#### IV Notices

#### NOTICES FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

##### European Commission

2021/C 100/01	Commission Notice – Guidelines for economic operators and market surveillance authorities on the practical implementation of Article 4 of Regulation (EU) 2019/1020 on market surveillance and compliance of products <sup>(1)</sup> .....	1
2021/C 100/02	Commission Notice – Guidance document for the application of Regulation (EU) 2019/515 of the European Parliament and of the Council on the mutual recognition of goods lawfully marketed in another Member State <sup>(1)</sup> .....	16
2021/C 100/03	Commission Notice – Guide on Articles 34-36 of the Treaty on the Functioning of the European Union (TFEU) <sup>(1)</sup> .....	38

EN

<sup>(1)</sup> Text with EEA relevance.



## IV

*(Notices)*

## NOTICES FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

## EUROPEAN COMMISSION

## COMMISSION NOTICE

**Guidelines for economic operators and market surveillance authorities on the practical implementation of Article 4 of Regulation (EU) 2019/1020 on market surveillance and compliance of products***(Text with EEA relevance)**(2021/C 100/01)*

## 1. INTRODUCTION

Regulation (EU) 2019/1020 of the European Parliament and of the Council on market surveillance and compliance of products <sup>(1)</sup> (‘the Regulation’) introduces a comprehensive framework to protect consumers from unsafe and non-compliant products and to provide a level playing field for economic operators.

The EU single market gives economic operators access to consumers and other end-users in all the Member States, provided they and their products meet EU legal requirements aimed at delivering safety, environmental performance and other public interests. Market surveillance authorities and the authorities in charge of controls on products entering the EU market <sup>(2)</sup> (‘border authorities’) have to verify and enforce those requirements. This can be challenging, especially for distance sales.

The new rules on market surveillance and product compliance should ensure compliance with the requirements. They help to create a level playing field, i.e. protect businesses manufacturing compliant products from unfair competition. They also spare market surveillance authorities from incurring undue costs in their investigations.

These guidelines concern the implementation of a key provision of the Regulation: Article 4 on the ‘tasks of economic operators regarding products subject to certain Union harmonisation legislation’ (see section 6). Article 4 requires in essence that for certain products placed on the EU market there must be an economic operator in the EU who on request provides the authorities with information or takes certain action. This will apply as from 16 July 2021 (Article 44 of the Regulation).

These guidelines provide guidance on how economic operators should implement Article 4:

- Section 2 explains its **scope** and **which economic operator** should act as the economic operator referred to in Article 4 for a given product,
- Section 3 clarifies the **tasks** of the economic operator referred to in Article 4, and
- Section 4 provides more detail on the **practical application** of Article 4 according to the type of economic operator acting as the economic operator referred to in Article 4.

Further, as the aim of Article 4 is to facilitate the work of the **market surveillance and border authorities**, Section 5 sets out how the authorities can make use of this requirement in practice.

<sup>(1)</sup> Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 (OJ L 169, 25.6.2019, p. 1).

<sup>(2)</sup> i.e. the authorities designated by Member States under Article 25(1) of the Regulation.

The guidelines are designed to help economic operators and authorities and facilitate consistent implementation. They concern the implementation of Article 4 only and do not apply to EU product legislation not covered by it, which may impose similar but different requirements <sup>(3)</sup>. They refer to requirements under EU harmonisation legislation as they apply at the date of adoption of this guidance. Comprehensive guidance on EU harmonisation legislation is available in the *Blue Guide*, to which these guidelines refer <sup>(4)</sup>. The Commission will update this guidance in the light of further legislative developments in other areas, like for instance the Digital Services Act <sup>(5)</sup>.

This document is purely for guidance – only the text of the Regulation itself has legal force. The guidelines reflect the views of the European Commission and as such are not legally binding. The binding interpretation of EU legislation is the exclusive competence of the Court of Justice of the European Union. The views expressed here cannot prejudice the position that the Commission might take before the Court of Justice. Neither the Commission nor anyone acting on its behalf is responsible for the use that might be made of the following information.

## 2. SCOPE AND APPLICATION

### 2.1. Scope

An economic operator referred to in Article 4 is required when a product:

- falls within the scope of one or more of the Directives or Regulations listed in Article 4(5) or other legislation that makes explicit reference to Article 4. This ‘sector-specific legislation’ covers the safety of toys, electrical equipment, radio equipment, electromagnetic compatibility, restricting hazardous substances in electrical and electronic equipment (‘RoHS’), energy-related products (‘ecodesign’), gas appliances, construction products, machinery, outdoor equipment (‘outdoor noise’), equipment for use in potentially explosive atmospheres (ATEX), pressure equipment, simple pressure vessels, pyrotechnic articles, recreational craft, measuring instruments, non-automatic weighing instruments, personal protective equipment and unmanned aircraft systems <sup>(6)</sup> (‘drones’ <sup>(7)</sup>), and
- is placed on the EU market <sup>(8)</sup>– i.e. made available (supplied for distribution, consumption or use on the EU market in the course of a commercial activity, whether in return for payment or free of charge) for the first time on the Union market <sup>(9)</sup>– on or after 16 July 2021 (Article 4(1) and Article 44 of the Regulation). Products offered for sale online, or through other means of distance sale, are considered to be made available on the market if the offer is targeted at end-users in the EU. An offer for sale is considered to be targeted at end-users in the EU if the relevant economic operator directs, by any means, its activities to a Member State (Article 6 of the Regulation) (this is determined case by case in the light of relevant factors such as the geographical areas to which dispatch is possible, the language(s) used for the offer or for ordering, means of payment, etc. <sup>(10)</sup>).

Thus, an economic operator who intends to place on the EU market on or after 16 July 2021 a product covered by Article 4 has first to ensure that there is an economic operator referred to in Article 4 in the EU. Otherwise, such products cannot be placed on the EU market on or after 16 July 2021.

<sup>(3)</sup> e.g. Directive 2014/90/EU of the European Parliament and of the Council of 23 July 2014 on marine equipment and repealing Council Directive 96/98/EC (OJ L 257, 28.8.2014, p. 146), which requires in its Article 13 manufacturers not located in the EU to appoint an authorised representative, and Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59), which requires in its Article 4 the designation of a responsible person in the EU. These are not covered by Article 4 or by these guidelines.

<sup>(4)</sup> Commission Notice – *Blue Guide on the implementation of EU product rules 2016* (OJ C 272, 26.7.2016, p. 1) or its successor document.

<sup>(5)</sup> Proposal for a Regulation of the European Parliament and of the Council on a Single Market For Digital Services (Digital Services Act) and amending Directive 2000/31/EC (COM(2020) 825 of 15.12.2020).

<sup>(6)</sup> As specified in Article 5(3) of Commission Delegated Regulation (EU) 2019/945 of 12 March 2019 on unmanned aircraft systems and on third-country operators of unmanned aircraft systems (OJ L 152, 11.6.2019, p. 1)

<sup>(7)</sup> Information on which Directives or Regulations might apply to a given product is available through YourEurope; [https://europa.eu/youreurope/business/product/product-rules-specifications/index\\_en.htm](https://europa.eu/youreurope/business/product/product-rules-specifications/index_en.htm)

<sup>(8)</sup> The geographical scope may be extended, e.g. once the Regulation is included in the annexes to the Agreement on the European Economic Area, it will include Iceland, Liechtenstein and Norway.

<sup>(9)</sup> See definitions (1) and (2) in Article 3 of the Regulation.

<sup>(10)</sup> Recital 15 of the Regulation. See the *Blue Guide* for more detail on placing on the market (e.g. as regards timing, including for products for which manufacturing has not yet been completed at the time of the offer, and products for trade fairs).

## 2.2. Determination of the economic operator referred to in Article 4

Four types of economic operator can act as the economic operator referred to in Article 4:

- A manufacturer <sup>(1)</sup> established in the EU
- An importer <sup>(2)</sup> (by definition established in the EU), where the manufacturer is not established in the Union
- An authorised representative <sup>(3)</sup> (by definition established in the EU) who has a written mandate from the manufacturer designating the authorised representative to perform the tasks set out in Article 4(3) on the manufacturer's behalf
- A fulfilment service provider <sup>(4)</sup> established in the EU where there is no manufacturer, importer or authorised representative established in the Union

Section 4 contains detail on these economic operators' role under sector-specific legislation and how this relates to their tasks under Article 4.

What economic operator acts as the economic operator referred to in Article 4 depends in particular on the supply chain. Box 1 provides a short guide on this and is followed by further explanation.

---

<sup>(1)</sup> Defined in Article 3(8) of the Regulation as 'any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under its name or trademark'.

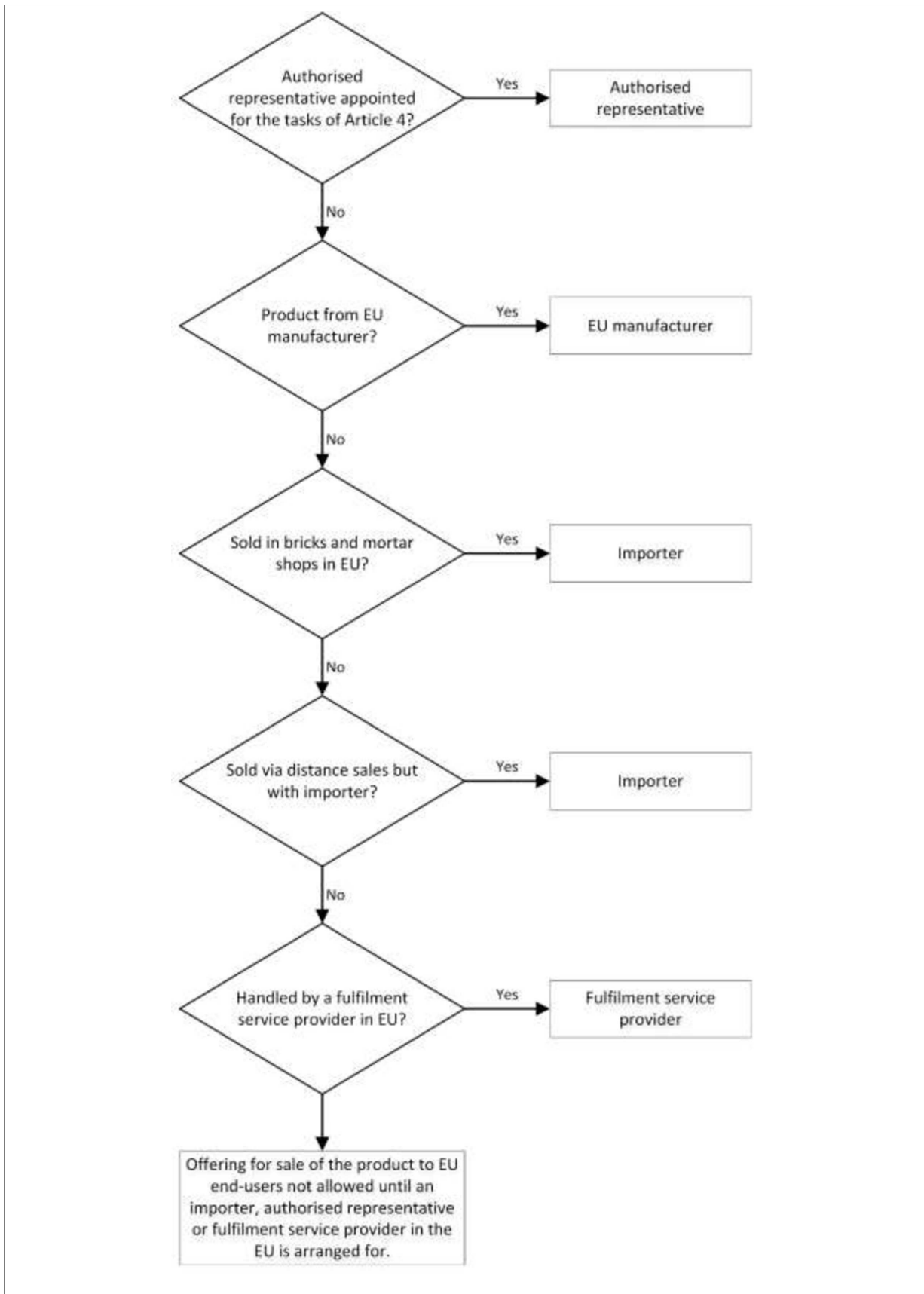
<sup>(2)</sup> Defined in Article 3(9) of the Regulation as 'any natural or legal person established within the Union who places a product from a third country on the Union market'.

<sup>(3)</sup> Defined in Article 3(12) of the Regulation as 'any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on its behalf in relation to specified tasks with regard to the manufacturer's obligations under the relevant Union harmonisation legislation or under the requirements of this Regulation'.

<sup>(4)</sup> Defined in Article 3(11) of the Regulation as 'any natural or legal person offering, in the course of commercial activity, at least two of the following services: warehousing, packaging, addressing and dispatching, without having ownership of the products involved, excluding postal services as defined in point 1 of Article 2 of Directive 97/67/EC of the European Parliament and of the Council, parcel delivery services as defined in point 2 of Article 2 of Regulation (EU) 2018/644 of the European Parliament and of the Council, and any other postal services or freight transport services'.

Box 1

The economic operator referred to in Article 4 in different supply chains



Step 1: If the manufacturer (whether or not established in the EU) has mandated in writing an **authorised representative** to carry out the specific tasks under Article 4, that representative is the economic operator referred to in Article 4. In other cases, it depends on the supply chain.

Step 2: Products from manufacturers established in the EU, whether sold online or in 'bricks and mortar' shops, are in general placed on the market by the EU manufacturer <sup>(15)</sup>. For such products, the **EU manufacturer** is the economic operator referred to in Article 4 (unless it has appointed an authorised representative for the tasks under Article 4).

Step 3: Products from manufacturers established outside the EU that are sold in 'bricks and mortar' shops in the EU are in principle placed on the EU market by an importer <sup>(16)</sup>. For such products, the **importer** is the economic operator referred to in Article 4 (unless the manufacturer has appointed an authorised representative for the tasks under Article 4). Section 4.2 explains what happens if there are multiple importers for the same type of product.

Step 4: For products from manufacturers established outside the EU offered for sale online (or through other distance sales), there may also be an importer, e.g. offering the product for sale online itself or selling it to a distributor who does so.

Step 5: If there is no importer but *a fulfilment service provider established in the EU is handling the product*, the **fulfilment service provider** is the economic operator referred to in Article 4 (unless the manufacturer has appointed an authorised representative for the tasks under Article 4). Unlike importers and authorised representatives, fulfilment service providers do not automatically have a formal connection with the manufacturer enabling them to fulfil the tasks of the economic operator referred to in Article 4. Therefore, they will need to make arrangements with economic operators to whom they are providing fulfilment services ('clients') to ensure that they first receive from the client, or directly from the manufacturer, the means to fulfil their obligations as the economic operator referred to in Article 4 (see Section 4.4);

Step 6: Where *the product is being shipped from outside the EU directly to an end-user in the EU*, if an **authorised representative** has been mandated in writing for the specific tasks under Article 4, it is the economic operator referred to in Article 4. If the manufacturer has not appointed an authorised representative, the product may not be offered for sale to EU end-users. The economic operator planning to offer the product for sale <sup>(17)</sup> to EU end-users will need to ensure that the manufacturer appoints an authorised representative for that product (see Box 2).

---

<sup>(15)</sup> The manufacturer is defined by Article 3 of the Regulation as 'any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under its name or trademark'. The importer is defined as 'any natural or legal person established within the Union who places a product from a third country on the Union market'. This implies that if the product is manufactured outside the EU, but a company located in the EU markets it under its name or trademark, that company is considered to be the manufacturer. And if that manufacturer places the product on the EU market, even if actual importation is done by another company, there is no 'importer' within the meaning of the Regulation.

<sup>(16)</sup> Except where the manufacturing takes place in the EU, while the manufacturer is not established in the EU. In such case, there is no manufacturer in the EU, nor an importer thus leaving only the options of authorised representative or fulfilment service provider as economic operator referred to in Article 4.

<sup>(17)</sup> Not be confused with an entity merely hosting the offer for sale online; for those, see Section 2.4.

## Box 2

**The perspective of an economic operator based outside the EU who plans to offer products for sale online to EU consumers or other end-users: How do I arrange for an economic operator referred to in Article 4? (example)**

- First, verify that the products are meant for the EU market and comply with EU legislation. If in doubt, contact the manufacturer.
- If this is in order, check with the manufacturer whether it has already appointed an authorised representative for these products.
- If so, make sure the authorised representative's name and contact details are indicated as required (see Section 2.3).
- If not, explore (in cooperation with the manufacturer) the following avenues:
  - if you intend to offer the products for sale on an online marketplace (see Section 2.4), does that marketplace offer authorised representative or fulfilment services?
  - if you already sell products for which an authorised representative in the EU or similar entity is required (e.g. cosmetics, medical devices and marine equipment), would that entity be interested to be an authorised representative for your products covered by Article 4?
  - are there relevant trade associations that (could) have access to information on existing authorised representatives (as a number of manufacturers of products covered by Article 4 may already have an authorised representative in the EU)?
- When you have found a potential authorised representative, make sure that the manufacturer authorises it to perform the required tasks (see Sections 3 and 4.3). Then make sure the representative's name and contact details are indicated as required (see Section 2.3).
- Where a fulfilment service provider is to act as economic operator referred to in Article 4, make practical arrangements, in particular ensuring that it receives the declaration of conformity/performance for the products in question. Then make sure its name and contact details are indicated as required (see Section 2.3)

**2.3. Information on the economic operator referred to in Article 4**

The **name** (or registered trade name/trademark) **and contact details** (including postal address) of the economic operator referred to in Article 4 must be indicated on at least one of the following (Article 4(4) of the Regulation):

- the product,
- its packaging, i.e. the sales packaging,
- the parcel, i.e. packaging to facilitate handling and transport,
- an accompanying document, e.g. declaration of conformity/performance <sup>(18)</sup>.

*NB: If the economic operator referred to in Article 4 is an EU manufacturer or an importer, this information is normally already required under sector-specific legislation (see Section 4). Those requirements may be more restrictive as to the place where the information is indicated, and have to be complied with.*

A **website address** may be given in addition to, but not instead of, a postal address (normally made up of a street/postbox, building number, postcode and town). Also, it is useful to include an email address and/or phone number to facilitate swift contacts with the relevant authorities.

<sup>(18)</sup> An indication in the (electronic) customs declaration is not sufficient, as this does not physically accompany the product.



It is possible that **multiple economic operators'** names and contact details are indicated on or with the product. While there may be no explicit requirement that these be preceded by 'manufactured by', 'imported by', 'represented by' or 'fulfilled by', the information should not mislead the market surveillance authorities. Where the operators' roles are not specified, the authorities will have to determine them themselves. Each economic operator should be able to prove its role. There is no obligation to translate the English terms 'manufactured by', 'imported by', 'represented by' or 'fulfilled by'; these English terms are considered easily understandable throughout the EU.

The name and contact details of the economic operator referred to in Article 4 have to be present when the product is declared for free circulation at **customs** (Article 26(1)(d) of the Regulation). Therefore, in case the product is aimed for release for free circulation in the EU and no further processing on the product is foreseen after its shipment <sup>(19)</sup>, economic operators outside the EU offering products for sale should make sure that they are indicated in the way described above, adding them (or having them added) prior to shipping if necessary.

#### 2.4. Products sold through online marketplaces

An online marketplace is a type of e-commerce service where products are offered for sale by multiple economic operators <sup>(20)</sup>. It allows economic operators on the one side, and end-users on the other side, to conclude sales transactions of products.

Article 4 applies to products sold through online marketplaces.

It places no specific obligation on the online marketplaces where they are merely providing intermediary services to third-party sellers and fall within the scope of Article 2(b) of Directive 2000/31/EC of the European Parliament and of the Council <sup>(21)</sup>. In the situation where an online marketplace intermediates the offer for sale to the EU end-users of a product covered by Article 4 for which there is no economic operator referred to in Article 4 <sup>(22)</sup> and obtains actual knowledge or awareness of illegal content (e.g. by means of a sufficiently precise and adequately substantiated notice from a market surveillance authority), that online marketplace can only rely on the liability exemption laid down in Article 14(1) of Directive 2000/31/EC, if upon obtaining such knowledge or awareness, it acts expeditiously to remove or to disable access to the illegal content in question.

Where an online marketplace is also a manufacturer, importer, authorised representative or fulfilment service provider, it could be the economic operator referred to in Article 4.

### 3. TASKS OF THE ECONOMIC OPERATOR REFERRED TO IN ARTICLE 4

This section categorises and provides guidance on the tasks of the economic operator referred to in Article 4. That economic operator, especially if it is an EU manufacturer or importer, may already have obligations under sector-specific legislation (depending on how it is classified) that fully or partly cover those tasks (see Section 4).

First, in accordance with Article 4(3)(a), the economic operator referred to in Article 4 has to perform a number of tasks when it **takes up its duties** or when a **new product** is added to its portfolio:

<sup>(19)</sup> Recital 53 of the Regulation reminds that Articles 220, 254, 256, 257 and 258 of Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code (OJ L 269, 10.10.2013, p. 1) provide that products entering the EU market that require further processing in order to be in compliance with the applicable EU harmonisation legislation shall be placed under the appropriate customs procedure allowing such processing by the importer.

<sup>(20)</sup> Article 4(1)(f) of Regulation (EU) No 524/2013 of the European Parliament and of the Council of 21 May 2013 on online dispute resolution for consumer disputes and amending Regulation (EC) No 2006/2004 and Directive 2009/22/EC (Regulation on consumer ODR) (OJ L 165, 18.6.2013, p. 1) defines an 'online marketplace' as follows: 'a service provider, as defined in point (b) of Article 2 of Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market ("Directive on electronic commerce"), which allows consumers and traders to conclude online sales and service contracts on the online marketplace's website'.

<sup>(21)</sup> Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (OJ L 178, 17.7.2000, p. 1).

<sup>(22)</sup> This falls under 'illegal activity or information' referred to in Article 14(1)(a) of Directive 2000/31/EC, because it does comply with Article 4 of the Regulation.

- verify that the declaration of conformity/performance has been drawn up and keep it – all sector-specific legislation covered by Article 4 requires such declarations <sup>(23)</sup>. As specified in the legislation covered by Article 4, they have to be kept for 10 years after the product has been placed on the market <sup>(24)</sup>. Where more than one legislative act applies to a product, a single declaration conformity is drawn up for all applicable acts together <sup>(25)</sup>, and
- verify that the technical documentation has been drawn up <sup>(26)</sup> and ensure that it can be made available to market surveillance authorities on request – where the economic operator referred to in Article 4 does not keep the documentation itself, this implies checking that the documentation exists and obtaining assurances from the manufacturer that it will share it on request, either with the economic operator referred to in Article 4 or with the market surveillance authorities directly (see below).

Second, in accordance with Article 4(3)(c) and (d), where the economic operator referred to in Article 4 has reason to believe that a product presents a **risk** <sup>(27)</sup>, it must:

- inform the relevant market surveillance authorities. It should do this in each Member State in which the product has been made available <sup>(28)</sup>; it is also important to inform them of the corrective action that has been or will be taken, and
- make sure that the necessary corrective action is taken immediately to remedy any case of non-compliance or, if that is not possible, to mitigate the risk (see below).

Finally, in accordance with Article 4(3)(a), (b) and (d), the economic operator referred to in Article 4 must take certain action **when asked** to do so by a market surveillance authority:

- provide that authority with the declaration of conformity/performance,
- provide the authority with the technical documentation or, where the economic operator referred to in Article 4 does not keep this documentation, ensure that the technical documentation is provided to the authority (in particular by the manufacturer),
- provide other information and documentation to demonstrate the conformity of the product (this may include e. g. certificates and decisions from a notified body) in a language that can be easily understood by the authority (to be negotiated with the authority – this could be a language other than the national language(s)),
- cooperate with the authority. The action required will depend on the authority's request, which has to be in accordance with the principle of proportionality (Article 14(2) of the Regulation), and
- make sure that the necessary corrective action is taken immediately to remedy any non-compliance with the EU harmonisation legislation applicable to the product in question or, if that is not possible, to mitigate the risks presented by the product. The action could involve bringing the product into conformity, withdrawing it or recalling it, as appropriate <sup>(29)</sup>. The economic operator referred to in Article 4 does not have to take corrective action or mitigate the risk itself if that economic operator is not obliged to do so under the sector-specific legislation, but must ensure that action is taken, e.g. by asking the manufacturer to respond to the request and verifying that it has done so.

<sup>(23)</sup> The declaration of performance for construction products; the declaration of conformity for others.

<sup>(24)</sup> Legislation on outdoor noise, machinery, and ecodesign specify 10 years from the last date of manufacture.

<sup>(25)</sup> Article 5 of Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ L 218, 13.8.2008, p. 82).

<sup>(26)</sup> All the legislation covered by Article 4 requires the manufacturer to draw up the technical documentation.

<sup>(27)</sup> Article 3(19) of the Regulation defines 'product presenting a risk' as 'a product having the potential to affect adversely health and safety of persons in general, health and safety in the workplace, protection of consumers, the environment, public security and other public interests, protected by the applicable Union harmonisation legislation, to a degree which goes beyond that considered reasonable and acceptable in relation to its intended purpose or under the normal or reasonably foreseeable conditions of use of the product concerned, including the duration of use and, where applicable, its putting into service, installation and maintenance requirements'.

<sup>(28)</sup> For contact information, see: [https://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation\\_en](https://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation_en)

<sup>(29)</sup> These options are specifically referred to in most sector-specific legislation for the manufacturer and importer; further potential corrective actions are listed in Article 16 of the Regulation.

The economic operator referred to in Article 4 should act within a **reasonable timeframe** or within any deadline set by the market surveillance authorities. It should provide the declaration of conformity/performance without delay and other documents within a reasonable period of time <sup>(30)</sup>.

If the economic operator referred to in Article 4 finds that it **cannot fulfil one or more of its tasks** due to a problem in its relations with the manufacturer <sup>(31)</sup> (e.g. the manufacturer does not respond to a request), an appropriate follow-up would be to remind the manufacturer of its obligations under EU legislation. If the problem persists, the logical consequence could be for it to take the necessary measures to cease being the economic operator referred to in Article 4 for the products in question, on the basis that it is unable to carry out its tasks under Article 4. In other words, in the case of:

- *an importer* – it could no longer place the products on the market,
- *an authorised representative* – it could try to end its relationship with the manufacturer,
- *a fulfilment service provider* – it could no longer handle the products, i.e. not dispatch them to end-users.

The economic operator referred to in Article 4 can be **sanctioned** <sup>(32)</sup> if it does not fulfil its tasks under Article 4. Any penalties must be effective, proportionate and dissuasive (Article 41(2) of the Regulation). The manufacturer remains responsible for the compliance of the product with sector-specific legislation and (like other actors in the supply chain) retains any legal obligations it has as regards products, guarantees, liability for defective products, etc. Article 4 does not impose additional legal obligations *vis-à-vis* consumers or other end-users.

#### 4. PRACTICAL IMPLICATIONS FOR ECONOMIC OPERATORS

The tasks of the economic operator referred to in Article 4 (as described in Article 4) are the same regardless of what type of economic operator is performing them, but the extent to which they overlap with the economic operator's other tasks under sector-specific legislation differs. All the 'Article 4 obligations' apply, regardless of what the sector-specific legislation requires of the economic operator in question. There are some sectoral differences, but most of the legislation closely follows the model legal provisions on economic operators' obligations <sup>(33)</sup>. This section highlights differences that affect the implementation of Article 4.

##### 4.1. Manufacturers established in the EU

A manufacturer is a natural or legal person that manufactures a product or has a product designed or manufactured, and markets that product under its name or trademark (Article 3 of the Regulation) <sup>(34)</sup>. If established in the EU, it is in principle the economic operator referred to in Article 4, unless it has appointed an authorised representative for the specific tasks under Article 4.

Manufacturers established in the EU already have responsibilities under sector-specific legislation that in general overlap with and go beyond the obligations under Article 4(3). An exception is that – unlike Article 4 – EU legislation on outdoor noise, machinery and ecodesign does not explicitly require them to inform the market surveillance authorities where they have reason to believe that a product covered by such legislation presents a risk. Manufacturers established in the EU and who are the economic operator referred to in Article 4 will however have to do this for the products covered by these legislative acts.

<sup>(30)</sup> Some sector-specific legislation (e.g. on toy safety and ecodesign) contains more detailed provisions on the timeliness with which certain economic operators are to provide the market surveillance authorities with certain documentation. These continue to apply.

<sup>(31)</sup> Or if a fulfilment service provider is hampered by a problem with its client or between its client and the manufacturer.

<sup>(32)</sup> Article 41(1) of the Regulation requires Member States to lay down rules on penalties in relation to this and certain other provisions of the Regulation.

<sup>(33)</sup> As laid down in Decision No 768/2008/EC; the *Blue Guide* provides further guidance on economic operators' obligations.

<sup>(34)</sup> Some sector-specific legislation contains a different definition of manufacturer. In particular, Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products (OJ L 285, 31.10.2009, p. 10) omits the 'or has a product designed or manufactured'.

Most sector-specific legislation requires that the manufacturer's name/trademark and address are indicated on the product; however:

- for some sectors, that information can in certain circumstances be indicated on the packaging or in an accompanying document instead,
- ecodesign legislation contains no such requirement,
- the legislation on outdoor noise and machinery requires instead that the name and address be indicated in the declaration of conformity <sup>(35)</sup> (or in the declaration of incorporation, in the case of partly completed machinery <sup>(36)</sup>) and that the declaration accompany the product <sup>(37)</sup>.

Therefore, in the exceptional case of a product covered by ecodesign legislation but not by the other sector-specific legislation covered by Article 4, Article 4 requires manufacturers established in the EU and who are the economic operator referred to in Article 4 to take the additional action of indicating their name and contact details.

#### 4.2. Importers

An importer is a natural or legal person established in the EU that places a product from a third country on the EU market (Article 3 of the Regulation). If there is an importer in the EU, it is in principle the economic operator referred to in Article 4, unless the manufacturer has appointed an authorised representative for the specific tasks under Article 4.

Sector-specific legislation in general imposes on the importer obligations that overlap with and go beyond the obligations laid down in Article 4(3) <sup>(38)</sup>. Again, an exception is that – unlike Article 4 – EU legislation on outdoor noise, machinery and ecodesign does not explicitly require importers to inform the market surveillance authorities where they have reason to believe that a product covered by such legislation presents a risk. Importers of products falling under that legislation and who are the economic operator referred to in Article 4 will however have to do this for the products covered by these legislative acts.

The sector-specific provisions on indicating the importer's name and contact details on or with the product are largely the same as for the manufacturer (see above). Therefore, only in exceptional cases does Article 4 require the importer who is the economic operator referred to in Article 4 to take the additional action of indicating its name and contact details.

Where multiple importers handle the same type of product, each is the economic operator referred to in Article 4 for the units it has placed on the EU market and will have to ensure that its name appears on or with those units, as required. This is already the case under sector-specific legislation where there are multiple importers for the same type of product. An individual product should thus in principle only bear the name of the relevant importer.

#### 4.3. Authorised representatives

An authorised representative is a natural or legal person established in the EU that has received a written mandate from a manufacturer to act on its behalf in relation to specified tasks with regard to the manufacturer's obligations under the relevant Union harmonisation legislation or under the requirements of Regulation (EU) 2019/1020 (Article 3 of the Regulation). If a manufacturer wants an authorised representative to act as the economic operator referred to in Article 4, it must ensure that the mandate includes all the tasks listed in Article 4(3). The authorised representative must have the appropriate means to be able to fulfil its tasks (Article 5(3) of the Regulation).

<sup>(35)</sup> Annex II to Directive 2000/14/EC of the European Parliament and of the Council of 8 May 2000 on the approximation of the laws of the Member States relating to the noise emission in the environment by equipment for use outdoors (OJ L 162, 3.7.2000, p. 1) and Part 1.A.1 of Annex II to Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast) (OJ L 157, 9.6.2006, p. 24), respectively.

<sup>(36)</sup> Part 1.B.1 of Annex II to Directive 2006/42/EC

<sup>(37)</sup> Article 4(1) of Directive 2000/14/EC and Article 5(1)(e) of Directive 2006/42/EC, respectively.

<sup>(38)</sup> EU legislation on outdoor noise (Article 4(2) of Directive 2000/14/EC) and machinery (Article 2(i) of Directive 2006/42/EC) does not use the term 'importer', but refers to 'any [other] person placing [the product] on the market'.

Sector-specific legislation often allows for the appointment of an authorised representative <sup>(39)</sup>. Where that option is taken up, it generally requires that the representative be mandated to do at least the following:

- keep the declaration of conformity/performance and the technical documentation at the disposal of the national market surveillance authorities for a specified period (in general 10 years in the case of the sector-specific legislation covered by Article 4),
- following a reasoned request, provide a competent national authority with all the information and documentation needed to demonstrate the conformity of a product, and
- cooperate with the competent national authorities, at their request, on any action to eliminate the risks posed by products <sup>(40)</sup> covered by its mandate.

Exceptions to this can be found in the legislation on outdoor noise, machinery and ecodesign, under which the authorised representative has different tasks, closer to those of the manufacturer.

Where a manufacturer has appointed an authorised representative under sector-specific legislation and wants it to act as the economic operator referred to in Article 4, it will therefore have to review its mandate to ensure that it includes all the tasks listed in Article 4(3). In particular, it may have to add tasks to be performed where the representative has reason to believe that a product presents a risk.

Similarly, where a manufacturer is planning to appoint an authorised representative with a view to facilitating compliance with Article 4, and where it wants to appoint an authorised representative within the framework of the sector-specific legislation, it will have to check the applicable sector-specific legislation for possible tasks in addition to those required by Article 4.

In addition to the tasks listed in Article 4(3), the authorised representative must also, on request, provide a market surveillance authority with a copy of its mandate in an EU language determined by the authority (Article 5(2) of the Regulation).

The legislation on outdoor noise, machinery and construction products requires that the authorised representative's name and contact details be indicated in the declaration of conformity/performance <sup>(41)</sup> that has to accompany these products <sup>(42)</sup>. In many other sectors, the legislation requires the manufacturer to indicate a contact address on or with the product; that address could be that of the authorised representative. Where the name and contact details of an authorised representative who is the economic operator referred to in Article 4 are not yet indicated on or with the product, the economic operator placing the product on the EU market should make sure these are added as required (for a smoother process, it could ask the manufacturer to do this systematically).

#### 4.4. Fulfilment service providers established in the EU

A fulfilment service provider is a natural or legal person offering at least two of the following services in the course of commercial activity, without having ownership of the products involved:

- warehousing,
- packaging,
- addressing, and
- dispatching.

<sup>(39)</sup> Except that for pyrotechnic articles. However, by virtue of Articles 4 and 5 of the Regulation, an authorised representative can be appointed for pyrotechnic articles; in that case its tasks will be those listed in Article 4.

<sup>(40)</sup> In the case of legislation on RoHS, on any action taken to ensure compliance (Article 8(b) of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88)), and in the case of legislation on drones, on any action to eliminate the non-conformity or the safety risks (Article 7(2)(c) of Commission Delegated Regulation (EU) 2019/945 of 12 March 2019 on unmanned aircraft systems and on third-country operators of unmanned aircraft systems (OJ L 152, 11.6.2019, p. 1)

<sup>(41)</sup> Annex II to Directive 2000/14/EC, Part 1.A.1 of Annex II to Directive 2006/42/EC, and Annex III to Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC (OJ L 88, 4.4.2011, p. 5), respectively.

<sup>(42)</sup> Article 4(1) of Directive 2000/14/EC, Article 5(1)(e) of Directive 2006/42/EC, and Article 7 of Regulation (EU) No 305/2011, respectively.

The qualifying services do not include postal services <sup>(43)</sup>, parcel delivery services <sup>(44)</sup> or any other postal or freight transport services (Article 3 of the Regulation).

Fulfilment service providers normally warehouse products in the EU, so that they can be swiftly delivered to EU consumers or other end-users as soon as they are ordered online. Thus, they provide services to other economic operators. On receiving an order, they package the product (unless it is already properly packaged for transport), affix the delivery address and dispatch it, either handing it over to a postal, parcel or transport service or delivering it themselves.

There is a wide range of operating scenarios for fulfilment services, but as described here they go beyond those of postal/parcel service providers (i.e. clearance and the sorting, transport and delivery of parcels). Where a natural or legal person offers both fulfilment services and postal/parcel delivery or freight transport services, Article 4 could be of relevance only in respect of the products handled by its fulfilment services.

Fulfilment service providers established in the EU are the economic operator referred to in Article 4 for products they handle in cases where there is no manufacturer, importer or authorised representative in the EU for those products. Therefore, before agreeing to provide the fulfilment service for a product covered by Article 4, they should verify with their client whether there is already one of the other types of economic operator in the EU for that product. If not, they will be the economic operator referred to in Article 4.

The sector-specific legislation does not refer to fulfilment service providers. Therefore, when acting as the economic operator referred to in Article 4, they will need to make arrangements with their clients to ensure that, before agreeing to provide the service, they receive from the client, or directly from the manufacturer, the means to fulfil the obligations, in particular:

- the declaration of conformity/performance for the products in question, and
- assurances of cooperation to help them carry out other tasks, such as:
  - providing technical documentation, and
  - taking corrective action when requested by the authorities.

The client should make sure that the service provider's name and contact details are indicated on or with the product, unless the manufacturer has already done so. The client can do this itself or have someone do it for them before the product is declared for free circulation at customs (see Section 2.3).

As with importers, there can be multiple fulfilment service providers for a given type of product. Each is the economic operator referred to in Article 4 for, and will have to have its name and contact details on or with, the units that it handles.

The manufacturer can appoint a fulfilment service provider as its authorised representative. In such cases, the parts of these guidelines concerning authorised representatives are relevant instead.

---

<sup>(43)</sup> As defined in Article 2(1) of Directive 97/67/EC of the European Parliament and of the Council of 15 December 1997 on common rules for the development of the internal market of Community postal services and the improvement of quality of service (OJ L 15, 21.1.1998, p. 14).

<sup>(44)</sup> As defined in Article 2(2) of Regulation (EU) 2018/644 of the European Parliament and of the Council of 18 April 2018 on cross-border parcel delivery services (OJ L 112, 2.5.2018, p. 19).

## Box 3

**I am a fulfilment service provider in the EU – what do I do? (example)**

A practical checklist would include the following:

- make existing and potential clients aware that, if any products covered by Article 4 they are selling must be linked to an economic operator referred to in Article 4. Point them to Article 4 and these guidelines,
- indicate to clients that you will be the economic operator referred to in Article 4 if there is no manufacturer, importer or authorised representative established in the EU (or, if you do not want to, make this clear and indicate that they cannot use your fulfilment services for those products unless there is a manufacturer, importer or authorised representative in the EU),
- if clients want you to act as the economic operator referred to in Article 4, check whether you are already performing this role for the same type of product for another client – if so, you already have everything you need; if not, decide the extent to which you will arrange what you need and the extent to which you want the client to do this for you,
- tell clients who want you to act as the economic operator referred to in Article 4 what they have to do before they can start using your fulfilment services, e.g. provide the manufacturer's contact details, declarations of conformity/performance, etc.,
- inform the clients once all arrangements have been made for you to act as the economic operator referred to in Article 4, so that they can start offering the products for sale.

## 5. MARKET SURVEILLANCE AND CONTROLS ON PRODUCTS ENTERING THE EU MARKET

### 5.1. Market surveillance

Market surveillance authorities have to perform appropriate checks on the characteristics of products on an adequate scale (Article 11(3) of the Regulation). In deciding what checks to perform, on which types of product and on what scale, they have to follow a risk-based approach (Ibid.) designed to achieve the greatest impact on the market.

After deciding what products to check, they may need to ask for **compliance documentation**. The economic operator referred to in Article 4 helps them obtain this information by facilitating their contact and cooperation with the manufacturer. Market surveillance authorities can contact the economic operator referred to in Article 4 directly even if it is located in another Member State <sup>(45)</sup>. They should be specific about the type of documents they need and the products for which they need them.

In the case of online or other distance sales where market surveillance authorities want to check compliance documentation without or before checking the product, they may not have the name and contact details of the economic operator referred to in Article 4. In such cases, they can contact the economic operator (as defined in Article 3 of the Regulation) offering the product for sale to ask for this <sup>(46)</sup>.

The economic operator referred to in Article 4 will serve as a contact to resolve **questions or problems** that go beyond documentation (Article 4(3)(d) of the Regulation). In such cases, the authorities should make it clear what they expect of it.

<sup>(45)</sup> If a market surveillance authority has difficulty in doing so, it can request assistance from an authority in the other Member State through the procedures and under the conditions laid down in Chapter VI of the Regulation.

<sup>(46)</sup> In accordance with Article 7(1) of the Regulation, economic operators (as defined in Article 3) have an obligation to cooperate with market surveillance authorities regarding certain actions. Recital 24 of the Regulation states that this includes providing the contact information of the economic operator with tasks regarding products subject to certain Union harmonisation legislation where requested by authorities and where this information is available to them.

The market surveillance authorities could contact the economic operator referred to in Article 4 on an issue that is relevant to the manufacturer whose product(s) are dealt with by it, but that does not specifically fall within the scope of Article 4, i. e. an issue that concerns legislation or products not covered by Article 4. Although Article 4 does not specifically provide for such requests, the economic operator referred to in Article 4 is encouraged to facilitate contacts between the authorities and manufacturers for these purposes.

### 5.2. Controls on products entering the EU market

Border authorities have a duty to control products entering the EU. They do so on the basis of risk analysis. When they perform physical checks on products covered by Article 4, it is recommended that they verify whether the name and contact details of the economic operator referred to in Article 4 are indicated on the product, the packaging, the parcel or any accompanying document (Article 4(4) of the Regulation). If this is not the case or they have cause to believe that for another reason the product does not comply with Article 4 <sup>(47)</sup>, they should suspend the release for free circulation, notify the market surveillance authorities (Article 26 of the Regulation) and await their reaction.

### 5.3. Non-compliance with Article 4

Given that the aim of Article 4 is mainly to facilitate checks on compliance documents, the absence of the name and contact details of the economic operator referred to in Article 4 is problematic, as it hampers market surveillance. It is also an indication that the product may not be meant for the EU market and/or may not comply with EU rules.

Therefore, where market surveillance authorities find, in the course of their investigations, that the name and contact details of the economic operator referred to in Article 4 are missing, they should require the relevant economic operator <sup>(48)</sup> to take corrective action. They also have the power to impose penalties (Article 14(4)(i) of the Regulation).

The same applies where the name and contact details of the economic operator referred to in Article 4 are indicated on or with a product, but the authorities find, in the course of their investigation, that these are false, e.g. the address does not exist or no such operator exists at the address.

The requirement to indicate the name and contact details of the economic operator referred to in Article 4 is not intended as the main object of an investigation. However, market surveillance authorities could take specific action in this area in the context of awareness-raising on it, possibly through EU-wide joint actions.

As mentioned in Section 3, the economic operator referred in Article 4 itself can be sanctioned if it does not comply with its obligations, and in particular if it does not cooperate (Article 41(1) of the Regulation). Any penalties have to be effective, proportionate and dissuasive (Article 41(2) of the Regulation).

---

<sup>(47)</sup> For example, where the name and contact details of the economic operator referred to in Article 4 are indicated on or with a product, but they find, in the course of their control, that these are false, e.g. the address does not exist or no such operator exists at the address.

<sup>(48)</sup> Normally, the manufacturer (unless, for example, the manufacturer did not intend for the products to be placed on the EU market, but another economic operator nevertheless did so). This will be possible only if the manufacturer can be identified, along with its contact information.



## 6. TEXT OF THE PROVISION

*Article 4***Tasks of economic operators regarding products subject to certain Union harmonisation legislation**

1. Notwithstanding any obligations set out in applicable Union harmonisation legislation, a product subject to legislation referred to in paragraph 5 may be placed on the market only if there is an economic operator established in the Union who is responsible for the tasks set out in paragraph 3 in respect of that product.

2. For the purposes of this Article, the economic operator referred to in paragraph 1 means any of the following:

- (a) a manufacturer established in the Union;
- (b) an importer, where the manufacturer is not established in the Union;
- (c) an authorised representative who has a written mandate from the manufacturer designating the authorised representative to perform the tasks set out in paragraph 3 on the manufacturer's behalf;
- (d) a fulfilment service provider established in the Union with respect to the products it handles, where no other economic operator as mentioned in points (a), (b) and (c) is established in the Union.

3. Without prejudice to any obligations of economic operators under the applicable Union harmonisation legislation, the economic operator referred to in paragraph 1 shall perform the following tasks:

- (a) if the Union harmonisation legislation applicable to the product provides for an EU declaration of conformity or declaration of performance and technical documentation, verifying that the EU declaration of conformity or declaration of performance and technical documentation have been drawn up, keeping the declaration of conformity or declaration of performance at the disposal of market surveillance authorities for the period required by that legislation and ensuring that the technical documentation can be made available to those authorities upon request;
- (b) further to a reasoned request from a market surveillance authority, providing that authority with all information and documentation necessary to demonstrate the conformity of the product in a language which can be easily understood by that authority;
- (c) when having reason to believe that a product in question presents a risk, informing the market surveillance authorities thereof;
- (d) cooperating with the market surveillance authorities, including following a reasoned request making sure that the immediate, necessary, corrective action is taken to remedy any case of non-compliance with the requirements set out in Union harmonisation legislation applicable to the product in question, or, if that is not possible, to mitigate the risks presented by that product, when required to do so by the market surveillance authorities or on its own initiative, where the economic operator referred to in paragraph 1 considers or has reason to believe that the product in question presents a risk.

4. Without prejudice to the respective obligations of economic operators under the applicable Union harmonisation legislation, the name, registered trade name or registered trademark, and contact details, including the postal address, of the economic operator referred to in paragraph 1 shall be indicated on the product or on its packaging, the parcel or an accompanying document.

5. This Article only applies in relation to products that are subject to Regulations (EU) No 305/2011, (EU) 2016/425 and (EU) 2016/426 of the European Parliament and of the Council, and Directives 2000/14/EC, 2006/42/EC, 2009/48/EC, 2009/125/EC, 2011/65/EU, 2013/29/EU, 2013/53/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU and 2014/68/EU of the European Parliament and of the Council.

## COMMISSION NOTICE

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

(Text with EEA relevance)

(2021/C 100/02)

## TABLE OF CONTENTS

	<i>Page</i>
1. INTRODUCTION .....	18
2. SCOPE OF THE REGULATION (ARTICLE 2 OF THE REGULATION) .....	18
2.1. Goods lawfully marketed in another Member State .....	19
2.1.1. Goods .....	19
2.1.2. Lawfully marketed in another Member State .....	19
2.2. 'Administrative decisions' under the Regulation .....	19
2.2.1. What is an administrative decision? .....	19
2.2.2. First criterion: national technical rules – basis for an administrative decision .....	20
2.2.3. Second criterion: the direct or indirect effect of the administrative decision is to restrict or deny market access in the Member State of destination .....	21
2.2.4. National technical rules and prior authorisation procedures .....	22
2.2.5. Some cases in which Regulation (EU) 2019/515 does not apply .....	23
3. HOW DOES MUTUAL RECOGNITION FUNCTION UNDER THE REGULATION? .....	23
3.1. Lawful marketing of goods in the Member State of origin .....	23
3.2. Selling the goods in another Member State .....	23
3.3. Information about the assessment .....	23
3.4. The 'mutual recognition declaration' (Article 4 of the Regulation) .....	23
3.4.1. Content and structure of the declaration .....	25
3.4.2. Language of the declaration .....	26
3.4.3. Who may draw up the declaration? .....	26
3.4.4. What happens if the declaration is only partially complete? .....	26
3.4.5. How and when can the declaration be used? .....	27
3.4.6. How to submit documents .....	27
3.5. Assessment by the competent authority (Article 5(1) of the Regulation) .....	27
3.5.1. Legitimate public interest grounds .....	28
3.5.2. The principle of proportionality .....	28
3.6. Temporary suspension of market access (Article 6 of the Regulation) .....	30
3.7. Administrative decision (Article 5(9)-5(13) of the Regulation) .....	31
3.8. Notifications to the Commission and the other Member States .....	31
3.9. Remedies against the administrative decision .....	32
3.10. What is SOLVIT? .....	32
3.11. SOLVIT and the problem-solving procedure under Article 8 of the Regulation .....	33

---

3.12. The Commission opinion in the context of the problem-solving procedure of Article 8 of the Regulation .....	34
3.13. The role of Product Contact Points (Article 9 of the Regulation) .....	34
3.14. Administrative cooperation (Article 10 of the Regulation) .....	35
4. PRIOR ASSESSMENT OF NATIONAL TECHNICAL RULES – DIRECTIVE (EU) 2015/1535 AND THE SINGLE MARKET CLAUSE .....	36
5. RELATIONSHIP BETWEEN REGULATION (EU) 2019/515 AND DIRECTIVE 2001/95/EC .....	37
5.1. Measures concerning products posing a risk to consumers' health and safety .....	37
5.2. Measures concerning consumer products posing other risks .....	37

## 1. INTRODUCTION

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

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

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

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

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

Article 36 TFEU states the following.

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

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

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

- Member States may not prohibit the sale on their territory of goods which are lawfully marketed in another Member State;
- Member States may restrict or deny the marketing of goods that have been lawfully marketed in another Member State, where such restriction or denial is justified on the grounds set out in Article 36 TFEU or on the basis of other reasons of public interest, recognised by the case-law of the Court.

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

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

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

<sup>(1)</sup> 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).

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

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

## 2.1. Goods lawfully marketed in another Member State

### 2.1.1. Goods

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

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

### 2.1.2. Lawfully marketed in another Member State

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

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

- **The first criterion** is that the goods or goods of that type must comply with the relevant rules applicable in the Member State of origin or must not be subject to any such rules in that Member State. Therefore, in the absence of relevant national technical rules related to the specific goods in the Member State of origin, the answer to the question of compliance of the goods with the national technical rules of that Member State is easier. When there are national technical rules in the Member State of origin, information about the characteristics of the goods and reference to the national law may in some cases be sufficient to show compliance. In other cases, a decision on prior authorisation could be necessary. It is necessary to bear in mind that Member States may follow very different systems for controlling goods before they are put on the market (prior authorisation procedures) or after they are put on the market (market surveillance). These different systems include situations where certain goods are not regulated at all and do not have to comply with national legal requirements. The fact that ‘compliance with the relevant rules’ for goods is conditioned by prior approval in one Member State does not necessarily mean that such approval would be required for the lawful marketing of the same goods in another Member State. The different requirements in Member States have no impact on the concept of lawful marketing.
- **The second criterion** of the concept of lawful marketing is that the goods were made available to end users in that Member State. Article 3(2) of the Regulation defines ‘making available on the market’ as ‘any supply of goods for distribution, consumption or use on the market within the territory of a Member State in the course of a commercial activity, whether in return for payment or free of charge’. Any document that contains: (i) unambiguous data to identify the goods or type of goods, and to identify suppliers, customers or end-users; and (ii) information on the date, such as an invoice, should be considered as necessary and sufficient evidence for the purpose of demonstrating that the criterion is fulfilled.

## 2.2. ‘Administrative decisions’ under the Regulation

### 2.2.1. What is an administrative decision?

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

- (a) the basis for the administrative decision is a national technical rule applicable in the Member State of destination; and
- (b) the direct or indirect effect of the administrative decision is to restrict or deny market access in the Member State of destination.

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

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

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

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

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

- a) it covers goods or aspects of goods that are not the subject of harmonisation at EU level;
- b) it either prohibits the making available of goods, or goods of a given type, on the market in that Member State, or it makes compliance with the provision compulsory, *de facto* or *de jure*, whenever goods, or goods of a given type, are made available on that market; and
- c) it does at least one of the following:
  - it lays down the characteristics required of goods or of goods of a given type, such as their levels of quality, performance or safety, or their dimensions, including the requirements applicable to those goods as regards the names under which they are sold, terminology, symbols, testing and test methods, packaging, marking or labelling and conformity assessment procedures <sup>(7)</sup>;
  - for the purpose of protecting consumers or the environment, it imposes other requirements on goods or goods of a given type that affect the life-cycle of the goods after they have been made available on the market in that Member State. These include conditions of use, recycling, reuse or disposal, where such conditions can significantly influence either the composition or nature of those goods, or the making available of them on the market in that Member State.

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

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

<sup>(7)</sup> This point also covers: (i) production methods and processes used in respect of agricultural products as referred to in the second subparagraph of Article 38(1) TFEU; (ii) the production methods and processes used in respect of products intended for human or animal consumption; and (iii) production methods and processes relating to other products, where these have an effect on their characteristics (see Article 2(3) of the Regulation).

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

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

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

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

- For instance, in its judgment in *Commission v Italy*, the Court held that a prohibition on the use of motorcycles towing trailers constitutes a measure having equivalent effect to quantitative restrictions on imports. This applies to the extent that the ban's effect is to hinder access to the market at issue for trailers specifically designed for motorcycles in as much as it has a considerable influence on the behaviour of consumers and prevents a demand from existing in the market at issue for such trailers <sup>(10)</sup>. Consumers, knowing that they are not permitted to use their motorcycle with a trailer specially designed for it, have practically no interest in buying that trailer <sup>(11)</sup>.
- Similarly, in *Mickelsson*, which concerned national regulations for the designation of navigable waters and waterways, the Court said that the restriction on the use of a product imposed by those regulations in the territory of a Member State could, depending on its scope, have a considerable influence on the behaviour of consumers. This may in turn affect the access of that product to the market of that Member State <sup>(12)</sup>. Consumers, knowing that the use permitted by such regulations is very limited, have only a limited interest in buying that product <sup>(13)</sup>. In that regard, the Court held that, where the national regulations for the designation of navigable waters and waterways have the effect of preventing users of personal watercraft from using them for the specific and inherent purposes for which they were intended or of greatly restricting their use, such regulations have the effect of hindering access to the domestic market in question for those goods and therefore constitute measures having equivalent effect to quantitative restrictions on imports <sup>(14)</sup>.
- The Court also considered as contrary to Article 34 TFEU the ban on affixing tinted films to the windows of motor vehicles, stating, amongst others, that potential customers, traders or individuals have practically no interest in buying such films in the knowledge that affixing them to the windscreen and windows alongside passenger seats in motor vehicles is prohibited <sup>(15)</sup>.

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

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

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

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

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

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

<sup>(10)</sup> Judgment of 10 February 2009, *Commission v Italy*, C-110/05, ECLI:EU:C:2009:66, paragraphs 56-58.

<sup>(11)</sup> Judgment of 10 February 2009, *Commission v Italy*, C-110/05, ECLI:EU:C:2009:66, paragraph 57.

<sup>(12)</sup> Judgment of 4 June 2009, *Mickelsson*, C-142/05, ECLI:EU:C:2009:336, paragraph 26.

<sup>(13)</sup> Judgment of 4 June 2009, *Mickelsson*, C-142/05, ECLI:EU:C:2009:336, paragraph 27.

<sup>(14)</sup> Judgment of 4 June 2009, *Mickelsson*, C-142/05, ECLI:EU:C:2009:336, paragraph 28.

<sup>(15)</sup> Judgment of 10 April 2008, *Commission v Portuguese Republic*, C-265/06, ECLI:EU:C:2008:210, paragraph 33.

<sup>(16)</sup> Judgment of 24 November 1993, *Keck and Mithouard*, Joined cases C-267/91 and C-268/91, ECLI:EU:C:1993:905, paragraphs 16 and 17. For more information about selling arrangements, see *Guide to the application of Treaty provisions governing the free movement of goods, 2010*, section 3.1.10.

<sup>(17)</sup> Judgment of 11 July 1974, *Procureur du Roi v Benoît and Gustave Dassonville*, Case 8-74, ECLI:EU:C:1974:82.

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

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

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

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

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

#### 2.2.4. National technical rules and prior authorisation procedures

National law sometimes requires prior authorisation before goods are placed on the market. A prior authorisation procedure means an administrative procedure under the law of a Member State requiring a competent authority of that Member State, on the basis of an application by an economic operator, to give its formal approval before goods may be made available on the market in that Member State (Article 3(7) of the Regulation).

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

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

<sup>(18)</sup> Judgment of 8 September 2009, *Budějovický Budvar, národní podnik*, C-478/07, ECLI:EU:C:2009:521, paragraphs 81-82.

<sup>(19)</sup> Judgment of 14 July 1994, *Peralta*, C-379/92, ECLI:EU:C:1994:296, paragraph 24.

<sup>(20)</sup> Judgment of 3 December 1998, *Ditlev Bluhme*, C-67/97, ECLI:EU:C:1998:584, paragraphs 19-20.

<sup>(21)</sup> *Ibidem*, paragraph 20.



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

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

Furthermore, the Regulation does not apply to decisions of a judicial nature taken by law enforcement authorities in the course of the investigation or prosecution of a criminal offence as regards the terminology, symbols or any material reference to unconstitutional or criminal organisations or offences of a racist, discriminatory or xenophobic nature (Article 2(5)(b) of the Regulation).

## 3. **HOW DOES MUTUAL RECOGNITION FUNCTION UNDER THE REGULATION?**

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

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

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

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

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

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

### 3.3. **Information about the assessment**

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

### 3.4. **The ‘mutual recognition declaration’ (Article 4 of the Regulation)**

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

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

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

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

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

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

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

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

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

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

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

<sup>(22)</sup> Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

### 3.4.1. Content and structure of the declaration

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

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

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

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

##### **Part I**

1. Unique identifier for the goods or type of goods: ... [Note: insert the goods identification number or other reference marker that uniquely identifies the goods or type of goods]
2. Name and address of the economic operator: ... [Note: insert the name and address of the signatory of Part I of the mutual recognition declaration: the producer and, where applicable, its authorised representative, or the importer, or the distributor]
3. Description of the goods or type of goods subject of the mutual recognition declaration: ... [Note: the description should be sufficient to enable the goods to be identified for traceability reasons. It may be accompanied by a photograph, where appropriate]
4. Declaration and information on the lawfulness of the marketing of the goods or that type of goods
  - 4.1. The goods or type of goods described above, including their characteristics, comply with the following rules applicable in ... [Note: identify the Member State in which the goods or that type of goods are claimed to be lawfully marketed]: ... [Note: insert the title and official publication reference, in each case, of the relevant rules applicable in that Member State and reference of the authorisation decision if the goods were subject to a prior authorisation procedure],  
...or  
the goods or type of goods described above are not subject to any relevant rules in ... [Note: identify the Member State in which the goods or that type of goods are claimed to be lawfully marketed].
  - 4.2. Reference of the conformity assessment procedure applicable to the goods or that type of goods, or reference of test reports for any tests performed by a conformity assessment body, including the name and address of that body (if such procedure was carried out or if such tests were performed): ...
5. Any additional information considered relevant to an assessment of whether the goods or that type of goods are lawfully marketed in the Member State indicated in point 4.1: ...
6. This part of the mutual recognition declaration has been drawn up under the sole responsibility of the economic operator identified under point 2.

Signed for and on behalf of:

(place and date):

(name, function) (signature):

##### **Part II**

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

- 7.2. Information that the goods or that type of goods are made available to the end users in the Member State indicated in point 4.1, including details of the date of when the goods were first made available to end users on the market in that Member State: ...
8. Any additional information considered relevant to an assessment of whether the goods or that type of goods are lawfully marketed in the Member State indicated in point 4.1: ...
9. This part of the mutual recognition declaration has been drawn up under the sole responsibility of ... [Note: insert the name and address of the signatory of Part II of the mutual recognition declaration: the producer and, where applicable, its authorised representative, or the importer, or the distributor]

Signed for and on behalf of:

(place and date):

(name, function) (signature):

#### 3.4.2. Language of the declaration

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

#### 3.4.3. Who may draw up the declaration?

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

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

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

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

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

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

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

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

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

The competent authority of the Member State of destination must inform the economic operator concerned ‘without delay’ when it intends to assess whether goods are lawfully marketed in another Member State and, if so, whether the legitimate public interests covered by the applicable national technical rule of the Member State of destination are adequately protected (Article 5(1) of the Regulation).

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

- the goods that are subject to the assessment;
- the applicable technical rule or prior authorisation procedure;
- the possibility of supplying a mutual recognition declaration.

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

#### 3.4.6. *How to submit documents*

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

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

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

- whether the goods or goods of that type are lawfully marketed in another Member State;
- and, if so, whether the legitimate public interests covered by the applicable national technical rule of the Member State of destination are adequately protected, having regard to the characteristics of the goods in question.

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

- 1) the national technical rule of the Member State of destination pursues a legitimate public interest objective, and
- 2) the restriction or denial of access is **proportionate**, meaning that the measure is **appropriate** for securing the attainment of the objective and **necessary** (it does not go beyond what is necessary for attaining the objective).

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

### 3.5.1. Legitimate public interest grounds

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

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

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

### 3.5.2. The principle of proportionality

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

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

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

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

The paragraphs below discuss some examples of the proportionality principle.

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

The Court assessed the **appropriateness** of measures to achieve the objective in the following cases among others<sup>(31)</sup>.

<sup>(23)</sup> The Court called them ‘mandatory requirements’ in *Cassis de Dijon*.

<sup>(24)</sup> Judgment of 20 February 1979, *Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein*, Case 120/78 ECLI:EU:C:1979:42, paragraph 13.

<sup>(25)</sup> Judgment of 12 June 2003, *Schmidberger*, C-112/00, ECLI:EU:C:2003:333: ‘restriction of trade in goods between Member States is justified by the legitimate interest in the protection of fundamental rights, in this case the protesters’ freedom of expression and freedom of assembly’.

<sup>(26)</sup> Judgment of 22 September 2016, *European Commission v Czech Republic*, C-525/14, ECLI:EU:C:2016:714.

<sup>(27)</sup> Judgment of 14 February 2008, *Dynamic Medien Vertriebs GmbH v Avides Media AG*, C-244/06, ECLI:EU:C:2008:85: prohibition of importation of Japanese cartoons called ‘Anime’ in DVD or video cassette format from the United Kingdom to Germany because these did not bear a label from that authority indicating the age from which the cartoons may be viewed, child protection being a justified base for the prohibition.

<sup>(28)</sup> Judgment of 1 July 2014, *Ålands Vindkraft AB v Energimyndigheten*, C-573/12, ECLI:EU:C:2014:2037; Judgment of 15 November 2005, *Commission v Austria*, C-320/03, ECLI:EU:C:2005:684.

<sup>(29)</sup> Guide to the application of Treaty provisions governing the free movement of goods, 2010, <https://op.europa.eu/en/publication-detail/-/publication/a5396a42-cbc8-4cd9-8b12-b769140091cd>

<sup>(30)</sup> Judgment of 15 November 2005, *Commission v Austria*, C-320/03, ECLI:EU:C:2005:684, paragraph 85.

<sup>(31)</sup> For more information, see Guide to the application of Treaty provisions governing the free movement of goods, 2010, <https://op.europa.eu/en/publication-detail/-/publication/a5396a42-cbc8-4cd9-8b12-b769140091cd>

- In *Ålands Vindkraft* the Court stressed that the use of renewable energy sources for the production of electricity is useful for the protection of the environment inasmuch as it contributes to the reduction in greenhouse gas emissions, which are among the main causes of climate change that the EU and its Member States have pledged to combat <sup>(32)</sup>.
- The Court held in *Commission v Italy* (trailers) that a prohibition to use motorcycles towing trailers is appropriate for the purpose of ensuring road safety <sup>(33)</sup>.
- The Court in *Dynamic Medien* held that there is no doubt that prohibiting the sale and transfer by mail order of image storage media which have not been examined and classified by the competent authority for the purpose of protecting young persons and which do not bear a label from that authority indicating the age from which they may be viewed constitutes a measure suitable to protect children against information and materials injurious to their well-being <sup>(34)</sup>.

b) Is the measure necessary to attain that objective?

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

- In *Commission v Czech Republic*, the Court pointed out that, in connection with the fight against fraud to ensure the protection of consumers in its territory, Member States are entitled to consider that hallmarks affixed in the territory of third countries do not offer a level of protection of consumers equivalent to the hallmarks affixed by independent bodies in the territory of the Member States (except where the Member State of import from third countries, which has an equivalent system of hallmarking, carries out checks of the goods and the results meet the requirement of that Member State <sup>(35)</sup>). The Court found, however, that the measure was not proportionate to the objective pursued, since the same objective could have been achieved by alternative, less restrictive measures. Firstly, the Czech authorities could have required documentary evidence from the importer to show the place where the hallmark in question was affixed and, as the case may be, the place where the precious metals concerned were put into free circulation and lawfully marketed in the EU. Secondly, the Czech authorities could have limited the refusal to recognise the WaarborgHolland hallmarks solely to circumstances in which an additional control of the precious metals by the Czech authorities is actually justified by the protection of consumers, in particular in cases of imports from third countries <sup>(36)</sup>.
- In *Ålands Vindkraft*, a wind farm located in Finland was refused the Swedish award of electricity certificates because such certificates were reserved only for green electricity production installations located in Sweden. The Court, however, found the measure proportionate, explaining that it did not appear that Sweden acted in breach of the principle of proportionality merely by reserving a support scheme using green certificates exclusively for green electricity produced in the national territory. Member States have a mandatory national renewable energy target (their fair share of effort) and the only electricity they can count towards such target is the one produced in their installations. As a result, Sweden was legitimately able to consider that such a territorial limitation does not go beyond what is necessary to attain the objective – pursued both by Directive 2009/28/EC of the European Parliament and of the Council <sup>(37)</sup> and by the national scheme that falls within the scope of that Directive – of increasing the production and, indirectly, the consumption of green electricity in the European Union <sup>(38)</sup>.

<sup>(32)</sup> Judgment of 1 July 2014, *Ålands Vindkraft AB v Energimyndigheten*, C-573/12, ECLI:EU:C:2014:2037, paragraph 78.

<sup>(33)</sup> Judgment of 10 February 2009, *Commission v Italy*, C-110/05, ECLI:EU:C:2009:66, paragraph 64.

<sup>(34)</sup> Judgment of 14 February 2008, *Dynamic Medien Vertriebs GmbH v Avides Media AG*, C-244/06, ECLI:EU:C:2008:85, paragraph 47.

<sup>(35)</sup> Judgment of 22 September 2016, *European Commission v Czech Republic*, C-525/14, ECLI:EU:C:2016:714, paragraphs 54 and 55.

<sup>(36)</sup> Judgment of 22 September 2016, *European Commission v Czech Republic*, C-525/14, ECLI:EU:C:2016:714, paragraphs 65 and 66.

<sup>(37)</sup> Directive 2009/28/EC of the European Parliament and of the Council of 23 April 2009 on the promotion of the use of energy from renewable sources and amending and subsequently repealing Directives 2001/77/EC and 2003/30/EC (OJ L 140, 5.6.2009, p. 16).

<sup>(38)</sup> Judgment of 1 July 2014, *Ålands Vindkraft AB v Energimyndigheten*, C-573/12, ECLI:EU:C:2014:2037, paragraph 104.

- In the *Dynamic Medien* case, the Court assessed the necessity of the measure as follows: as far as the substantive scope of the prohibition was concerned, the law on the protection of young persons does not preclude all forms of marketing of unchecked image storage media. It is clear from the decision that it is permissible to import and sell such image storage media to adults by way of distribution channels involving personal contact between the supplier and the purchaser, which thus ensures that children do not have access to the image storage media concerned. In the light of those factors, it appears that the rules at issue in the main proceedings do not go beyond what is necessary to attain the objective pursued by the Member State concerned <sup>(39)</sup>.
  
- In Case C-265/06, *Commission of the European Communities v Portuguese Republic*, the Court found that the fight against crime and ensuring road safety may constitute overriding reasons in the public interest capable of justifying a hindrance to the free movement of goods. Although the ban of affixing tinted film to the windows of passenger or goods vehicles ‘does indeed appear to be likely to facilitate such inspection and, therefore, appropriate to attain the objectives of fighting crime and ensuring road safety, it does not follow that it is necessary to attain those objectives or that there are no other less restrictive means of doing so’ <sup>(40)</sup>. The necessity of the ban was further undermined when the authorities admitted that motor vehicles fitted from the outset with tinted windows within the limits laid down by Council Directive 92/22/EEC <sup>(41)</sup> are allowed on their territory. Furthermore, there is a wide range of tinted films (from transparent film to film which is almost opaque) which means that at least some films, namely those with a sufficient degree of transparency, permit the desired visual inspection of the interior of motor vehicles. Therefore, the Court concluded that the ban on tinted films in vehicles was excessive and therefore disproportionate with respect to the objectives pursued <sup>(42)</sup>.

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

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

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

- a) under normal or reasonably foreseeable conditions of use, the goods pose a serious risk to human safety or health or to the environment, including one where the effects are not immediate, which requires rapid intervention by the competent authority; or
  
- b) the making available of the goods, or of goods of that type, on the market in that Member State is generally prohibited in that Member State on grounds of public morality or public security.

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

<sup>(39)</sup> Judgment of 14 February 2008, *Dynamic Medien Vertriebs GmbH v Avides Media AG*, C-244/06, ECLI:EU:C:2008:85, paragraph 48.

<sup>(40)</sup> Judgment of 10 April 2008, *Commission v Portuguese Republic*, C-265/06, ECLI:EU:C:2008:210, paragraphs 38-41.

<sup>(41)</sup> Council Directive 92/22/EEC of 31 March 1992 on safety glazing and glazing materials on motor vehicles and their trailers (OJ L 129, 14.5.1992, p. 11).

<sup>(42)</sup> Judgment of 10 April 2008, *Commission v Portuguese Republic*, C-265/06, ECLI:EU:C:2008:210, paragraphs 38-48.



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

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

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

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

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

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

- a) the national technical rule on which the administrative decision is based;
- b) the legitimate public interest grounds justifying the application of the national technical rule on which the administrative decision is based;
- c) the technical or scientific evidence considered by the competent authority of the Member State of destination, including, where applicable, any relevant changes in the state of the art that have occurred since the national technical rule came into force;
- d) a summary of the arguments (if any) put forward by the economic operator concerned that are relevant for assessing whether the goods have been lawfully marketed and whether the legitimate public interests covered by the applicable national technical rule of the Member State of destination are adequately protected, having regard to the characteristics of the goods in question;
- e) the evidence demonstrating that the administrative decision is appropriate for the purpose of achieving the objective pursued and that it does not go beyond what is necessary in order to attain that objective.

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

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

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

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

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

- temporary suspensions (Article 6(2) of the Regulation);
- administrative decisions (Article 5(9) of the Regulation).

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

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

---

<sup>(43)</sup> See also Section 3.5.1.

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

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

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

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

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

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

### 3.9. Remedies against the administrative decision

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

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

### 3.10. What is SOLVIT?

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

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

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

<sup>(44)</sup> In accordance with Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (OJ L 11, 15.1.2002, p. 4).

<sup>(45)</sup> In accordance with Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

<sup>(46)</sup> Commission Recommendation 2013/461/EU of 17 September 2013 on the principles governing SOLVIT (OJ L 249, 19.9.2013, p. 10).

<sup>(47)</sup> Section IV, point 2 of Recommendation 2013/461/EU.

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

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

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

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

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

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

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

<sup>(48)</sup> Section III, point 6 of Recommendation 2013/461/EU.

<sup>(49)</sup> Section V.A, point 1 of Recommendation 2013/461/EU.

<sup>(50)</sup> Section V.B, point 2 of Recommendation 2013/461/EU.

<sup>(51)</sup> Section V.C, point 2 of Recommendation 2013/461/EU.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- a) the principle of mutual recognition and the application of the Regulation in the territory of their Member State, including information on the assessment of goods procedure under Article 5 of the Regulation;
- b) the direct contact details of the competent authorities in their Member State, including the particulars of the authorities responsible for supervising the implementation of the national technical rules applicable in the territory of their Member State;
- c) the remedies and procedures available in the territory of their Member State in the event of a dispute between the competent authority and an economic operator, including the problem-solving procedure set out in Article 8 of the Regulation.

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

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

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

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

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

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

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

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

---

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

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

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

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

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

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

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

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

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

To raise awareness among national authorities and economic operators of the principle of mutual recognition, Member States should consider providing for clear and unambiguous 'single market clauses' in their national technical rules (recital 16 of the Regulation), to reduce the risk of these rules raising regulatory barriers to trade <sup>(55)</sup>, and facilitate the application of that principle. In the notification procedure under Directive (EU) 2015/1535, the Commission regularly recommends, where appropriate, that the authorities of the Member State concerned include the single market clause in the notified draft, as set out in *The Goods Package: Reinforcing trust in the single market* <sup>(56)</sup>. The following is a further clarified version of the clause.

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

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

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

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

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

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

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

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

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

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

### 5.2. Measures concerning consumer products posing other risks

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

---

---

<sup>(57)</sup> OJ L 11, 15.1.2002, p. 4.

**COMMISSION NOTICE****Guide on Articles 34-36 of the Treaty on the Functioning of the European Union (TFEU)****(Text with EEA relevance)**

(2021/C 100/03)

**PREFACE**

The long-term action plan for better implementation and enforcement of single market rules (hereinafter 'Enforcement Action Plan')<sup>(1)</sup>, adopted in March 2020, puts the single market and its enforcement at its core. To improve compliance and avoid market segmentation, Action 1 of the Enforcement Action plan foresees that the Commission will provide more specific guidance tools for national authorities and stakeholders. It also foresees the update of the Guidance on the application of Articles 34-36 TFEU.

Hence, it is in this context that the Commission has updated this Guidance. This document intends to facilitate the application of EU law on the free movement of goods, step up enforcement, and contribute to the benefits that the Internal Market for goods can bring to EU businesses and consumers. It intends to provide a better understanding of the application of Articles 34-36 of the Treaty on the Functioning of the European Union (TFEU) in light of the most relevant jurisprudence of the Court of Justice of the European Union (CJEU) in this area. It also intends to reinforce a coherent application of the principle of the free movement of goods throughout the Internal Market, helping addressing any remaining obstacle and preventing new ones to raise.

This guide builds on the previous edition of 2009<sup>(2)</sup> and incorporates the most relevant CJEU jurisprudence of the last eleven years to ensure it provides a comprehensive and up-to-date overview of the application of Articles 34 to 36 TFEU. However although it summarises the relevant case law and provides supplementary commentary, it cannot be considered exhaustive. The guide is not a legally binding document.

EU legislation and rulings mentioned in this guide can be found in *Eur-Lex*<sup>(3)</sup>, and judgments of the Court are also available on the webpage of the CJEU<sup>(4)</sup>.

---

<sup>(1)</sup> COM(2020) 94, 10.3.2020.

<sup>(2)</sup> Guide to the application of Treaty provisions governing the free movement of goods (2010).

<sup>(3)</sup> <http://eur-lex.europa.eu/en/index.htm>

<sup>(4)</sup> <http://curia.europa.eu/juris/recherche.jsf?language=en> It should be noted that the guide uses the numbering of the TFEU also when referring to judgments of the Court rendered under the EC Treaty.



## TABLE OF CONTENTS

	<i>Page</i>
1 THE ROLE AND IMPORTANCE OF THE FREE MOVEMENT OF GOODS IN THE INTERNAL MARKET .....	41
2. THE TREATY PROVISIONS .....	41
3. THE SCOPE OF ARTICLE 34 TFEU .....	42
3.1. General conditions .....	42
3.1.1. Non-harmonised area .....	42
3.1.2. Meaning of 'goods' .....	42
3.1.3. Addressees .....	43
3.1.4. Active and passive measures .....	44
3.2. Territorial scope .....	45
3.3. Cross-border trade .....	45
3.4. Types of restrictions under Article 34 TFEU .....	46
3.4.1. Quantitative restrictions .....	46
3.4.2. Measures of equivalent effect .....	46
3.4.2.1. Restrictions on use .....	47
3.4.2.2. Discriminatory selling arrangements .....	48
3.5. The Mutual Recognition principle .....	49
4. TYPES OF MEASURES .....	51
4.1. National provisions related to the act of import (import licences, inspections and controls) .....	51
4.2. Obligations to appoint a representative or to provide storage facilities in the importing Member State .....	51
4.3. National bans on specific products/substances .....	52
4.4. Price measures .....	53
4.5. Authorisation procedures .....	55
4.5.1. Type approval .....	55
4.5.2. Car registration .....	56
4.6. Advertising restrictions .....	56
4.7. Technical regulations containing requirements as to the presentation of goods (weight, composition, presentation, labelling, form, size, packaging) .....	57
4.8. Indications of origin, quality marks, incitement to buy national products .....	58
4.9. Restrictions on distance selling (internet sales, mail order, etc.) .....	59
4.10. Deposit obligations .....	59
4.11. Reimbursement and parallel imports .....	60
4.12. Obligation to use the national language .....	62
4.13. Restrictions on the importation of goods for personal use .....	62
5. AGRICULTURAL PRODUCTS .....	63
6. EXPORT RESTRICTIONS (ARTICLE 35 TFEU) .....	64
6.1. Definition of 'Exports' .....	64
6.2. Quantitative restrictions and measures having equivalent effect .....	64

7.	JUSTIFICATIONS FOR RESTRICTIONS TO TRADE .....	66
7.1.	Article 36 TFEU .....	66
7.1.1.	Public morality, policy and security .....	67
7.1.2.	Protection of the health and life of humans, animals and plants (precautionary principle) .....	68
7.1.3.	Protection of national treasures possessing artistic, historic or archaeological value .....	69
7.1.4.	Protection of industrial and commercial property .....	69
7.2.	Mandatory requirements .....	71
7.2.1.	Protection of the environment .....	72
7.2.2.	Consumer protection .....	73
7.2.3.	Other mandatory requirements .....	73
7.3.	Proportionality test .....	74
7.4.	Burden of proof.....	76
8.	RELATIONSHIP TO OTHER FREEDOMS AND ARTICLES OF THE TREATY RELATED TO THE FREE MOVEMENT OF GOODS .....	76
8.1.	Fundamental freedoms .....	76
8.1.1.	Article 45 TFEU – Freedom of movement of workers .....	76
8.1.2.	Articles 49 and 56 TFEU – Freedom to establish and provide services .....	77
8.1.3.	Articles 63 TFEU et seq. – Free movement of capital and payments .....	79
8.2.	Other relevant Treaty articles .....	79
8.2.1.	Article 18 TFEU – Non-discrimination based on nationality .....	79
8.2.2.	Articles 28 and 30 TFEU – The customs union .....	80
8.2.3.	Article 37 TFEU – State monopolies .....	80
8.2.4.	Article 107 TFEU – State aids .....	82
8.2.5.	Article 110 TFEU – Tax provisions .....	83
8.2.6.	Article 351 TFEU .....	84
9.	ENFORCEMENT OF ARTICLES 34 AND 35 TFEU .....	84
9.1.	Direct effect – private enforcement .....	84
9.2.	SOLVIT .....	84
9.3.	Infringement proceedings under Articles 258 and 260 TFEU .....	85
9.3.1.	Infringement procedure .....	85
9.3.2.	Complaints .....	85
10.	RELATED INSTRUMENTS OF SECONDARY LAW .....	86
10.1.	Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services .....	86
10.2.	Regulation (EU) 2019/515 – The ‘Mutual Recognition’ Regulation .....	87
10.3.	Regulation (EC) No 2679/98 – The ‘strawberry’ Regulation .....	87

## 1. THE ROLE AND IMPORTANCE OF THE FREE MOVEMENT OF GOODS IN THE INTERNAL MARKET

The internal market is one of the EU's greatest achievements. It is at the heart of the European project, has fuelled economic growth in the past decades, and brought concrete benefits to European consumers and businesses. A well-functioning single market becomes even more essential during sanitary crises such as the COVID-19 pandemic. It allows products to circulate freely, ensuring their availability, and reaching those that are most in need EU wide.

The integrity of the single market is also a necessary tool to fuel collective recovery for all Member States' economies. In this regard, the internal market cannot only facilitate that EU citizens enjoy a wider choice of products, but also gives EU economic operators a large domestic market, stimulating trade and competition, and improving efficiency.

Today's internal market makes it easy to buy and sell products across the 27 EU Member States with a total population of more than 450 million people and gives consumers a wide choice of products. At the same time, the free movement of goods is beneficial for business, as around 75 % of intra-EU trade is in goods. The single European marketplace helps EU businesses to build a strong platform in an open, diverse and competitive environment. This strength fosters growth and job creation in the EU and gives European businesses the resources they need in order to be successful in the global market. A properly functioning internal market for goods is thus a critical element for the current and future prosperity of the EU in a globalised economy <sup>(5)</sup>.

From a legal perspective, the principle of the free movement of goods has been a key element in creating and developing the internal market. Articles 34 to 36 TFEU define the scope and content of the principle by prohibiting unjustified restrictions on intra-EU trade. However, they are only applicable in non-harmonised areas.

Harmonisation legislation consists of EU regulations and directives which aim at creating common rules which are applicable in all Member States. While regulations are directly applicable and binding acts which must be applied in their entirety across the EU, directives are acts which only set out a goal that all Member States must achieve. Harmonised legislation has specified the meaning of the internal market in many areas and has thereby framed the principle of the free movement of goods in concrete terms for specific products. Nevertheless, the fundamental function of the Treaty principles as a key anchor and a safety net for the internal market remains unaltered.

Today's free movement of goods incorporates many policies and fits smoothly into a responsible internal market which guarantees an easy access to high-quality products, combined with a high degree of protection of other public interests.

## 2. THE TREATY PROVISIONS

The main Treaty provisions governing the free movement of goods are:

- Article 34 TFEU, which relates to intra-EU imports and prohibits 'quantitative restrictions and all measures having equivalent effect' between Member States; it reads '*Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States*'.
- Article 35 TFEU, which relates to exports from one Member State to another and similarly prohibits 'quantitative restrictions and all measures having equivalent effect'. It reads; '*Quantitative restrictions on exports, and all measures having equivalent effect, shall be prohibited between Member States*'.
- Article 36 TFEU, which provides for derogations to the internal market freedoms of Articles 34 and 35 TFEU that are justified on certain specific grounds. It reads: '*The provisions of Articles 34 and 35 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.*'

<sup>(5)</sup> Communication from the Commission: The Single Market in a changing world – A unique asset in need of renewed political commitment (COM(2018) 772 final).

The Treaty chapter on the prohibition of quantitative restrictions between Member States contains, also in Article 37 TFEU, rules on the adjustment of State monopolies of a commercial character. Its role and relation to Articles 34-36 TFEU is briefly described in Chapter 6 of this guide, which also covers other Treaty articles.

### 3. THE SCOPE OF ARTICLE 34 TFEU

#### 3.1. General conditions

##### 3.1.1. *Non-harmonised area*

While Articles 34-36 TFEU lay the groundwork for the principle of the free movement of goods, they are not the only legal yardstick for assessing the compatibility of national measures with internal market rules. These Treaty articles apply where a given product is not covered by EU harmonising legislation or is only partially covered by EU harmonising legislation. This would be the case should the technical specifications of a given product or its conditions of sale be subject to harmonisation by means of directives or regulations adopted by the EU. Therefore, the main rule is that where a matter has been the subject of exhaustive harmonisation at EU level, any national measure relating thereto must be assessed in the light of the provisions of that harmonising measure and not in the light of primary law <sup>(6)</sup>. However, in instances of incorrect transposition of secondary legislation which aims to remove barriers to the internal market, individuals who have been harmed by such incorrect transposition may rely on Treaty provisions on free movement of goods to render their Member State liable for a breach of EU law <sup>(7)</sup>.

Hence, where secondary legislation is relevant, any national measure relating thereto must be assessed in the light of the harmonising provisions <sup>(8)</sup>. This is due to the fact that harmonising legislation can be understood as substantiating the free movement of goods principle by establishing actual rights and duties to be observed in the case of specific products.

This can be seen in Case C-292/12 *Ragn-Sells*, which concerned certain contract documents drawn up by a municipality in the course of a procedure for awarding a service concession for the collection and transport of waste produced on its territory. The Court stated that as Regulation (EC) No 1013/2006 of the European Parliament and of the Council on shipments of waste <sup>(9)</sup> aims to provide a harmonised set of procedures whereby movements of waste can be limited in order to secure protection of the environment, it was not necessary to examine whether the national measure complied with Articles 34 TFEU to 36 TFEU <sup>(10)</sup>. Even after several decades of dedicated activity on the part of the EU legislator in providing a system of harmonised rules, the Treaty provisions on free movement of goods have not become redundant; their scope is still remarkable. It is not uncommon for certain areas to not be harmonised at all or only be subject to partial harmonisation. Where harmonising legislation cannot be identified or is not exhaustive, Articles 34-36 TFEU operate. In this respect, the Treaty articles act as a safety net, guaranteeing that any obstacle to trade within the internal market can be scrutinised as to its compatibility with EU law.

##### 3.1.2. *Meaning of 'goods'*

Articles 34 and 35 TFEU encompass imports and exports of goods and products of any type. Any good may be covered by the Treaty articles, provided it has economic value: 'by goods, within the meaning of the Treaty, there must be understood products which can be valued in money and which are capable, as such, of forming the subject of commercial transactions' <sup>(11)</sup>.

<sup>(6)</sup> See, for instance, Case C-573/12 *Ålands Vindkraft* [2014] EU:C:2014:2037, para. 57 and Case C-242/17 *L.E.G.O* [2018] ECLI:EU:C:2018:804, para. 52.

<sup>(7)</sup> Case C-445/06 *Danske Slagterier v Bundesrepublik Deutschland* [2009] ECLI:EU:C:2009:178, para. 26.

<sup>(8)</sup> Case C-309/02 *Radlberger Spitz* [2004] ECLI:EU:C:2004:799, para. 53.

<sup>(9)</sup> Regulation (EC) No 1013/2006 of the European Parliament and of the Council of 14 June 2006 on shipments of waste (OJ L 190, 12.7.2006, p. 1).

<sup>(10)</sup> Case C-292/12 *Ragn-Sells* [2013] ECLI:EU:C:2013:820, paras. 49-50.

<sup>(11)</sup> Case 7/68 *Commission v Italy* [1968] ECLI:EU:C:1968:51.

The Court of Justice has clarified in its jurisprudence the proper designation of particular products. For example, works of art must be seen as goods <sup>(12)</sup>. Coins which are no longer in circulation as currency would equally fall under the definition of goods, as would bank notes and bearer cheques <sup>(13)</sup>; although donations in kind would not <sup>(14)</sup>. Waste is to be regarded as a good, regardless of its ability to be recycled or reused <sup>(15)</sup>. Electricity <sup>(16)</sup> and natural gas <sup>(17)</sup> are also considered goods, as are human blood, plasma and medicinal products derived thereof <sup>(18)</sup>.

However, it is important to draw a legal distinction between goods and services as per the Treaty freedoms <sup>(19)</sup>. For instance, while fish are certainly goods, fishing rights and angling permits are not necessarily covered by the free movement of goods principle. They rather constitute a 'provision of a service' within the meaning of the Treaty provisions relating to the freedom to provide services <sup>(20)</sup>. If a State measure affects both the freedom to provide services and the free movement of goods, the Court may examine the measure in relation to both freedoms. For example, in Case C-591/17 *Austria v Germany* concerning an infrastructure use charge and the relief from motor vehicle tax for vehicles registered in Germany, the Court considered it in light of Article 34 TFEU and the freedom to provide services under Article 56 TFEU. It went on to also consider the case with regard to the principles of non-discrimination under Article 18 TFEU and Article 92 TFEU which prohibits any discrimination in the area of transport <sup>(21)</sup>.

### 3.1.3. Addressees

Articles 34-36 TFEU deal with measures taken by the Member States. These provisions have been interpreted broadly to bind not only national authorities, but also all other authorities of a country, including local and regional authorities <sup>(22)</sup>, as well as the judicial or administrative bodies of a Member State <sup>(23)</sup>. This evidently covers measures taken by all bodies established under public law as 'public bodies'. In addition, Articles 34-36 TFEU may apply to measures taken by non-state actors or other bodies established under private law, provided they fulfil certain sovereign functions or their activities may be attributed to the State otherwise. Indeed, measures taken by a professional body which has been granted regulatory and disciplinary powers by national legislation in relation to its profession may fall within the scope of Article 34 TFEU <sup>(24)</sup>.

The same applies to activities of bodies established under private law but which are set up by law, mainly financed by the Government or compulsory contribution from undertakings in a certain sector and/or from which members are appointed by the public authorities or supervised by them and can be therefore attributed to the State <sup>(25)</sup>. In *Fra.bo*, the Court found Article 34 TFEU to apply horizontally to a private-law certification body. Products certified by this body were considered by national authorities to be compliant with national law. And, by virtue of this competence *acquired de facto*, the certification body had the power to regulate the entry of products, in this case copper fittings, into the German market <sup>(26)</sup>. The Court has acknowledged that public statements made by a State official, despite lacking legal force, are attributable to a Member State and may constitute an obstacle to the free movement of goods. Specifically, such instances would occur if the addressees of the statements can reasonably suppose that these are positions taken by the official with the authority of his office <sup>(27)</sup>.

<sup>(12)</sup> Case 7/68 *Commission v Italy* [1968] ECLI:EU:C:1968:51; Case 7/78 *R. v Thompson, Johnson and Woodiwiss* [1978] ECLI:EU:C:1978:209.

<sup>(13)</sup> Case C-358/93 *Bordessa* [1995] ECLI:EU:C:1995:54.

<sup>(14)</sup> Case C-318/07 *Persche*, [2009] ECLI:EU:C:2009:33, para. 29.

<sup>(15)</sup> Case C-2/90, *Commission v Belgium* [1992] ECLI:EU:C:1992:310, paras. 23-28.

<sup>(16)</sup> Case C-393/92 *Municipality of Almelo and others v NV Energiebedrijf Ijsselmij* [1994] ECLI:EU:C:1994:171.

<sup>(17)</sup> Case C-159/94 *Commission v France* [1997] ECLI:EU:C:1997:501.

<sup>(18)</sup> Case C-421/09 *Humanplasma GmbH v Republic of Austria* [2010] ECLI:EU:C:2010:760, paras. 27-30, as confirmed in C-296/15 *Medisanus* [2017] ECLI:EU:C:2017:431, para. 53.

<sup>(19)</sup> See Section 7.1.2 for additional information concerning the relationship between Articles 34-36 and 56 TFEU.

<sup>(20)</sup> Case C-97/98 *Peter Jägerskiöld v Torolf Gustafsson* [1999] ECLI:EU:C:1999:515.

<sup>(21)</sup> Case C-591/17 *Austria v Germany* [2019] ECLI:EU:C:2019:504, para. 39-40.

<sup>(22)</sup> Case C-1/90 *Aragonesa de Publicidad v Departamento de sanidad* [1991] ECLI:EU:C:1991:327.

<sup>(23)</sup> Case 434/85 *Allen & Hanburys* [1988] ECLI:EU:C:1988:109, para. 25; Case C-227/06 *Commission v Belgium* ECLI:EU:C:2008:160, para. 37.

<sup>(24)</sup> See Joined Cases 266/87 and 267/87 *R v Royal Pharmaceutical Society of Great Britain* [1989] ECLI:EU:C:1989:205; Case C-292/92 *Hünernmund* [1993] ECLI:EU:C:1993:932.

<sup>(25)</sup> See Case 249/81 *Commission v Ireland (Buy Irish)* [1982] ECLI:EU:C:1982:402; Case 222/82 *Apple and Pear Development Council* [1983] ECLI:EU:C:1983:370; Case C-325/00 *Commission v Germany* [2002] ECLI:EU:C:2002:633; Case C-227/06 *Commission v Belgium* [2008] ECLI:EU:C:2008:160.

<sup>(26)</sup> Case C-171/11 *Fra.bo Spa v Deutsche Vereinigung des Gas und Wasserfaches eV (DVGW) — Technisch Wissenschaftlicher Verein* [2012] ECLI:EU:C:2012:453, paras. 31-32.

<sup>(27)</sup> Case C-470/03 *AGM-Cosmet SRI* [2007] ECLI:EU:C:2007:213.

Although the term ‘Member State’ has been interpreted broadly, it generally does not apply to ‘purely’ private measures, or measures taken by private individuals or companies, as these are not attributable to the State. In Case C-265/95 *Commission v France*, however, the Court considered France’s failure to take all necessary and proportionate measures to prevent damaging actions taken by private individuals, in this case French farmers who had sabotaged imported agricultural goods, as a violation of Article 34 TFEU read together with Article 4(3) TFEU <sup>(28)</sup>. Though the restriction occurred as a result of the actions of individuals, a Member State was found in violation of EU law for not taking sufficient measures to protect the free movement of these goods.

Finally, Article 34 TFEU has also been applied to measures taken by the EU institutions. With regard to judicial review the EU legislature must, however, be allowed broad discretion. As a result, the legality of a measure taken by an EU institution may only be questioned if the measure is manifestly inappropriate, in regard to the objective which the competent institution is seeking to pursue <sup>(29)</sup>.

#### 3.1.4. Active and passive measures

Often characterised as a defence right, the application of Article 34 TFEU to national measures which hamper cross-border trade necessarily presupposes activity on the part of a State. As a result, the measures falling within the scope of Article 34 TFEU consist primarily of binding provisions of Member States’ legislation. However, non-binding measures can also constitute a breach of Article 34 TFEU <sup>(30)</sup>. This is the case of administrative practices that may produce an obstacle to the free movement of goods if it has a certain degree of consistency and generality <sup>(31)</sup>.

Examples of administrative practises considered as measures of equivalent effect by the Court of Justice include: a systematic refusal to grant type approval for postal franking machines, which was by its nature protectionist and discriminatory <sup>(32)</sup>; systematically classifying as medicinal products by function and, in the absence of marketing authorisation, withdrawing from the market products based on medicinal herbs lawfully produced or marketed as food supplements or dietary products in other Member States <sup>(33)</sup>; automatically classifying vitamin preparations as ‘medicinal products’ after being lawfully manufactured or marketed as food supplements in the other Member States where they contain three times more vitamins <sup>(34)</sup>; and requiring that enriched foodstuffs lawfully produced or marketed in other Member States may be marketed in Denmark only if it is shown that such enrichment with nutrients meets a need in the Danish population <sup>(35)</sup>.

In view of Member States’ obligations under Article 4(3) TFEU, which requires them to take all appropriate measures to ensure fulfilment of the Treaty obligations and the ‘*effet utile*’ of EU law, the Court has found Article 34 TFEU to prohibit not only State action amounting to an infringement, but inaction, too. This may arise where a Member State refrains from adopting the measures required in order to deal with obstacles to the free movement of goods, and the specific obstacle may even emanate from action by private individuals. In Case C-265/95, France was held responsible for actions of national farmers seeking to restrict the import of agricultural goods from neighbouring Member States by preventing the interception of lorries transporting these goods or destructing their loaded goods. The non-intervention of national authorities against these acts was considered an infringement of Article 34 TFEU, as Member States are obliged to ensure the free movement of products in their territory by taking the measures necessary and appropriate for the purposes of preventing any restriction due to the acts of private individuals <sup>(36)</sup>.

<sup>(28)</sup> Case C-265/95 *Commission v France* [1997] ECLI:EU:C:1997:595.

<sup>(29)</sup> Joined Cases C-154/04 and C-155/04 *Alliance for Natural Health* [2004] ECLI:EU:C:2004:848, para. 47 and 52.

<sup>(30)</sup> Case 249/81 *Commission v Ireland* (Buy Irish) [1982] ECLI:EU:C:1982:402; Case C-227/06 *Commission v Belgium* [2008] ECLI:EU:C:2008:160.

<sup>(31)</sup> Case 21/84 *Commission v France* [1985] ECLI:EU:C:1985:184; Case C-387/99 *Commission v Germany* [2004] ECLI:EU:C:2004:235, para. 42; Case C-88/07 *Commission v Spain* [2009] ECLI:EU:C:2009:123; Case C-192/01 *Commission v Denmark* [2003] ECLI:EU:C:2003:492, para. 40.

<sup>(32)</sup> Case 21/84 *Commission v France* [1985] ECLI:EU:C:1985:184, para. 11-15.

<sup>(33)</sup> Case C-88/07 *Commission v Spain* [2009] ECLI:EU:C:2009:123, para. 54-66, 116.

<sup>(34)</sup> Case C-387/99 *Commission v Germany* [2004] ECLI:EU:C:2004:235, para. 83.

<sup>(35)</sup> Case C-192/01 *Commission v Denmark* [2003] ECLI:EU:C:2003:492, para. 40.

<sup>(36)</sup> Case C-265/95 *Commission v France* [1997] ECLI:EU:C:1997:595, para. 31; see also Case C-112/00 *Schmidberger* [2003] ECLI:EU:C:2003:333, para. 60 especially on possible justifications (freedom of expression and freedom of assembly).

Moreover, Article 34 TFEU may create an obligation of result. This duty is infringed if a Member State falls short of the objectives due to its inactivity or insufficient activity. In Case C-309/02, for example, the Court found in a preliminary ruling that German rules were contrary to Article 34 TFEU for failing to ensure that private parties could effectively participate in a German mandatory take-back system for one-way beverage packaging <sup>(37)</sup>.

### 3.2. Territorial scope

The obligation to respect the provisions of Articles 34-36 TFEU applies to all Member States of the EU. In addition, Treaty provisions may apply to European territories for whose external relations a Member State is responsible and also to overseas territories dependent upon or otherwise associated with a Member State <sup>(38)</sup>.

For a detailed account of the territories to which Article 34 TFEU applies, see the Annex to this guide.

With regard to EFTA countries that are contracting parties to the EEA Agreement and Turkey, the provisions of specific agreements and not those of the TFEU govern the trade in goods between these countries and the Member States. Hence, products referred to in Article 8(3) of the EEA Agreement and originating in Iceland, Liechtenstein, and Norway enjoy free movement in the EU by virtue of Article 11 of the EEA Agreement. Industrial products originating in Turkey enjoy free movement in the EU by virtue of Articles 5 to 7 of Decision No 1/95 of the EC-Turkey Association Council on implementing the final phase of the Customs Union <sup>(39)</sup>.

### 3.3. Cross-border trade

The scope of Article 34 TFEU is limited to obstacles in trade between the Member States. A cross-border element is therefore necessary for a case to be evaluated under this provision. Purely national measures, affecting only domestic goods, fall outside the scope of Articles 34-36 TFEU. For a measure to fulfil the cross-border requirement, it is sufficient that it is capable of either indirectly or potentially hindering intra-EU trade <sup>(40)</sup>.

Theoretically, the required cross-border element in the Treaty provisions does not prevent Member States from treating their domestic products less favourably than imported products ('reverse discrimination'), though this is unlikely to occur in practice. Although Article 34 TFEU is applicable where a domestic product is re-imported, or leaves the Member State but is imported back <sup>(41)</sup>, it does not apply in cases where the sole purpose of re-import is to circumvent the domestic rules <sup>(42)</sup>.

The cross-border requirement may also be fulfilled if the product is merely transiting the Member State in question. In this regard, Article 36 TFEU clearly refers to restrictions on 'goods in transit' as being covered by the provisions of Articles 34 and 35 TFEU.

The principle of the free movement of goods applies to products originating in Member States and those from third countries in free circulation in Member States. Article 29 TFEU sets out that products coming from third countries are considered to freely circulate in a Member State provided the import formalities have been complied with and relevant customs duties levied. In Case C-30/01 *Commission v United Kingdom*, the Court confirmed that under Article 29(2) TFEU, measures taken for the purposes of intra-Union trade applies in the same way to products originating in Member States and those originating from third countries <sup>(43)</sup>.

According to established case law, a national measure will not fall outside the scope of the prohibition in Articles 34-35 TFEU only because the hindrance which it creates is slight and because it is possible for products to be marketed in other ways <sup>(44)</sup>. Even if a measure is of relatively minor economic significance, is only applicable to a very limited geographical part of the national territory <sup>(45)</sup> or only affects a limited number of imports/exports or economic operators, it may constitute a prohibited measure having equivalent effect.

<sup>(37)</sup> Case C-309/02 *Radlberger Spitz* [2004] ECLI:EU:C:2004:799, para. 80.

<sup>(38)</sup> See Article 355 TFEU.

<sup>(39)</sup> OJ L 35, 13.2.1996, p. 1.

<sup>(40)</sup> Case 8/74 *Dassonville* [1974] ECLI:EU:C:1974:82, para. 5.

<sup>(41)</sup> Case 78/70 *Deutsche Grammophon v Metro* [1971] ECLI:EU:C:1971:59.

<sup>(42)</sup> Case 229/83 *Leclerc v Au Ble Vert* [1985] ECLI:EU:C:1985:1.

<sup>(43)</sup> Case C-30/01 *Commission v United Kingdom* [2003] ECLI:EU:C:2003:489, paras 49-54.

<sup>(44)</sup> Case 177/82 *Van de Haar* [1984] ECLI:EU:C:1984:144; 269/83 *Commission v France* [1985] ECLI:EU:C:1985:115; 103/84 *Commission v Italy* [1986] ECLI:EU:C:1986:229.

<sup>(45)</sup> Case C-67/97 *Ditlev Blühme* [1998] ECLI:EU:C:1998:584.

However, State measures which are too uncertain and indirect to have a restrictive effect on trade between Member States can be distinguished from the above <sup>(46)</sup>. In Case C-297/05, for instance, the Court considered that an administrative formality by the Netherlands involving the identification of vehicles imported into the country prior to their registration was ‘unlikely to have any deterrent effect whatsoever on the import of a vehicle into the Netherlands or to make the import of vehicles less attractive’ <sup>(47)</sup>. Thus, this measure fell outside the scope of Article 34 TFEU.

### 3.4. Types of restrictions under Article 34 TFEU

#### 3.4.1. Quantitative restrictions

Quantitative restrictions have been defined as measures which amount to a total or partial restraint on imports or goods in transit <sup>(48)</sup>. Examples of such measures include an outright ban on imports or a quota system <sup>(49)</sup>. In other words, quantitative restrictions apply when certain import or export ceilings have been reached. However, only non-tariff quotas are caught by Article 34 TFEU, since tariff quotas are covered by Article 30 TFEU, which prohibits customs duties on imports and exports and charges having equivalent effect.

A quantitative restriction may be based on statutory provisions or merely on an administrative practice. Thus, even a covert or hidden quota system will be caught by Article 34 TFEU.

#### 3.4.2. Measures of equivalent effect

The term ‘measure having equivalent effect’ is much broader in scope than a quantitative restriction. While it is not easy to draw an exact dividing line between quantitative restrictions and measures of equivalent effect, this is not of much practical importance given that the rules generally apply in the same way to quantitative restrictions as to measures of equivalent effect.

In *Dassonville*, the Court of Justice set out an interpretation on the meaning and scope of measures of equivalent effect <sup>(50)</sup>:

‘All trading rules enacted by Member States which are capable of hindering, directly or indirectly, actually or potentially, intra-Community trade are to be considered as measures having an effect equivalent to quantitative restrictions.’

This definition has been confirmed in subsequent case law with minor variations. The term ‘trading rules’ does usually not appear nowadays, as the *Dassonville* formula is actually not limited to trading rules but also embraces, for instance, technical regulations and even non-binding acts.

In the *Dassonville* case, the Court stressed that the most important element determining whether a national measure is caught under Article 34 TFEU is its effect (...*capable of hindering, directly or indirectly, actually or potentially...*) <sup>(51)</sup>. In consequence, there is no need for a discriminatory element in order for a national measure to be caught under Article 34 TFEU.

The landmark ruling by the Court in *Cassis de Dijon* <sup>(52)</sup> affirmed this approach. By acknowledging that the differences between the national rules of the Member States could inhibit trade in goods, the Court confirmed that Article 34 TFEU could also catch national measures which apply equally to domestic and imported goods. In this case, Member States could derogate by having recourse not only to Article 36 TFEU but also to the mandatory requirements, a concept which was first enshrined in this ruling.

<sup>(46)</sup> Case C-379/92 *Peralta* [1994] ECLI:EU:C:1994:296; Case C-44/98 *BASF* [1999] ECLI:EU:C:1999:440. Cf. also C-20/03 *Burmanjer* [2005] ECLI:EU:C:2005:307.

<sup>(47)</sup> Case C-297/05 *Commission v Netherlands* [2007] ECLI:EU:C:2007:531, para. 63.

<sup>(48)</sup> Case 2/73 *Riseria Luigi Geddo v Ente Nazionale Risi* [1973] ECLI:EU:C:1973:89.

<sup>(49)</sup> Case 13/68 *Salgoil SpA v Italian Ministry of Foreign Trade* [1968] ECLI:EU:C:1968:54.

<sup>(50)</sup> Case 8/74 *Dassonville* [1974] ECLI:EU:C:1974:82. For historical background, see also Commission Directive 70/50/EEC of 22 December 1969 based on the provisions of Article 33(7), on the abolition of measures which have an effect equivalent to quantitative restrictions on imports and are not covered by other provisions adopted in pursuance of the EEC Treaty (OJ L 13, 19.1.1970, p. 29).

<sup>(51)</sup> Case 8/74 *Dassonville* [1974] ECLI:EU:C:1974:82, para. 5.

<sup>(52)</sup> Case 120/78 *Rewe Zentrale v Bundesmonopolverwaltung für Branntwein* [1979] ECLI:EU:C:1979:42.



In summary, Article 34 TFEU applies to national measures which discriminate against imported goods (so-called distinctly applicable measures) and to national measures which in law seem to apply equally to both domestic and imported goods, but in fact impose an additional burden on imports (so-called indistinctly applicable measures).<sup>(53)</sup> This burden stems from the fact that the imported goods are required to comply with two sets of rules – those laid down by the Member State of manufacture, and those laid down in the Member State of importation.

Subsequently, measures of equivalent effect to a quantitative restriction have also come to include any other measures capable of hindering market access<sup>(54)</sup>. In this regard, the Court has stated the following in *Commission v Spain*<sup>(55)</sup>: 'it is clear from the case law that a measure, even if it does not have the purpose or effect of treating less favourably products from other Member States, is included in the concept of a measure equivalent to a quantitative restriction within the meaning of Article 34 TFEU if it hinders access to the market of a Member State of goods originating in other Member States.'

The assumption underlining the so-called market access test is that conditions of access are somehow more difficult for imported products. Often, the Court puts emphasis on assessing whether the measure concerned may have a considerable influence on the behaviour of consumers by making it less attractive to purchase an imported product<sup>(56)</sup>.

Hence, the definition of measures of equivalent effect is wide and constantly evolving. For instance, the Court held in Case C-591/17 *Austria v Germany* that an infrastructure use charge and the relief from motor vehicle tax for vehicles registered in Germany was liable to restrict the access to the German market of goods from other Member States and thus constituted a restriction to the free movement of goods. It pointed out that even though the infrastructure use charge was not levied on goods carried as such, it was nonetheless capable of affecting goods that are delivered using passenger vehicles weighing up to 3,5 tonnes registered in a Member State other than Germany<sup>(57)</sup>.

Another example of the dynamic nature of the concept of a measure of equivalent effect is Case C-573/12 *Ålands Vindkraft*, which concerned a national support scheme for green electricity. Certificates under the scheme were only awarded to Swedish renewables producers, even if the electricity they supplied or used may have included imported electricity. The Court held that such a scheme may hinder at least indirectly and potentially imports of (green) electricity from other Member States. The Court pointed out that failure by a Member State to adopt adequate measures to prevent barriers to the free movement of goods that have been created is just as likely to obstruct intra-EU trade as is a positive act. Hence, the Court held that the legislation at issue constituted a measure having equivalent effect to a quantitative restriction on imports<sup>(58)</sup>.

#### 3.4.2.1. Restrictions on use

One category of restrictions has been developed in the Court's case law rather recently: restrictions on use. Such restrictions are characterised as national rules which allow the sale of a product while restricting its use to a certain extent. Restrictions on use may include restrictions relating to the purpose or the method of the particular use, the context or time of use, the extent of the use or the types of use. Such measures may in certain circumstances constitute measures having equivalent effect to a quantitative restriction.

There are three cases which could be named in this connection. First, *Commission v Portugal*<sup>(59)</sup>, which concerned a Portuguese law prohibiting the affixing of tinted films to the windows of motor vehicles. The Commission argued that any potential customers, traders or individuals would not buy such film since they knew that they could not affix it to the

<sup>(53)</sup> Examples of measures of equivalent effect include composition requirements or any other product requirements, limiting channels of distribution and giving preference to domestic goods.

<sup>(54)</sup> See, inter alia, Case C-110/05 *Commission v Italy* [2009], ECLI:EU:C:2009:66, para 37, Case C-456/10 *ANETT* [2012], ECLI:EU:C:2012:241 and Case C-148/15 *Deutsche Parkinson Vereinigung*, [2016], ECLI:EU:C:2016:776.

<sup>(55)</sup> Case C-428/12 *Commission v Spain* [2014], ECLI:EU:C:2014:218, para. 29.

<sup>(56)</sup> Case C-110/05 *Commission v Italy* [2009], ECLI:EU:C:2009:66, para 56.

<sup>(57)</sup> Case C-591/17 *Austria v Germany* [2019] ECLI:EU:C:2019:504, para. 125-134.

<sup>(58)</sup> Case C-573/12 *Ålands Vindkraft* [2014] ECLI:EU:C:2014:2037, para 67-75, 82 and 119. However, the Court considered the measure at issue justified on grounds of the objective of promoting the use of renewable energy sources for the production of electricity

<sup>(59)</sup> Case C-265/06 *Commission v Portugal* [2008] ECLI:EU:C:2008:210.

window of motor vehicles <sup>(60)</sup>. The Court seemed to accept this argument and held that ‘...potential customers, traders or individuals have practically no interest in buying them in the knowledge that affixing such film to the windscreen and windows alongside passenger seats in motor vehicles is prohibited’ <sup>(61)</sup>. As a result, it reached the conclusion that Portugal was in breach of its obligations under Article 34 TFEU.

Secondly, in *Commission v Italy* <sup>(62)</sup>, the question was whether Italy, by maintaining rules which prohibit motorcycles from towing trailers, had failed to fulfil its obligations under Article 34 TFEU. In so far as trailers which were specifically designed to be towed by motorcycles were concerned, the Court held that the possibility for their use other than with motorcycles was limited, and that consumers, knowing that they were not allowed to use their motorcycle with a trailer specifically designed for it, had practically no interest in buying such a trailer <sup>(63)</sup>. As a result, the prohibition in question constituted a breach of Article 34 TFEU.

Finally, *Mickelsson and Roos* <sup>(64)</sup> concerned a reference for a preliminary ruling which raised the question of whether Articles 34 and 36 TFEU precluded Swedish rules on the use of personal watercraft. Under Swedish regulations, the use of such crafts on waterways not deemed to be general navigable waterways and on waters on which the county administrative board had not permitted the use thereof was prohibited and punishable by a fine. The Court stated that where such rules have the effect of preventing users of personal watercraft from using them for the specific and inherent purposes for which they were intended or of greatly restricting their use, they have the effect of hindering the access to the domestic market for those goods. As the actual possibilities for the use of personal watercraft in Sweden were merely marginal, the national rules constituted measures of equivalent effect to quantitative restrictions <sup>(65)</sup>. However, the Court held that the national rules could be justified on grounds of protection of the environment if certain additional requirements were complied with <sup>(66)</sup>. In *Sandström*, the Court further specified the conditions on which a prohibition to use a personal watercraft on waters other than designated waterways may be allowed <sup>(67)</sup>.

As seen above, the assessment of restrictions on use is also governed by the market-access test. In addition to assessing the market effects of the measure, the Court also assesses the effects it may have on consumer behaviour. It may be summarised that measures which impose a total ban on the use of a specific product, which prevent its use for the specific and inherent purposes for which it was intended, or which greatly restrict its use, may fall within the scope of Article 34 TFEU.

#### 3.4.2.2. Discriminatory selling arrangements

Almost twenty years after *Dassonville*, the Court found it necessary to revise its jurisprudence on the scope of ‘measures having equivalent effect’ under Article 34 TFEU. Thus, the Court created the concept of selling arrangements in the landmark *Keck and Mithouard* judgment, which concerned French legislation prohibiting resale at a loss <sup>(68)</sup>. It stated that ‘the application to products from other Member States of national provisions restricting or prohibiting certain selling arrangements is not such as to hinder directly or indirectly, actually or potentially, trade between Member States within the meaning of the *Dassonville* judgment, so long as:

1. Those provisions apply to all relevant traders operating within the national territory, and;
2. They affect in the same manner, in law and in fact, the marketing of domestic products and of those from other Member States.’ <sup>(69)</sup>

Rules that lay down requirements to be met by goods continue to be treated under *Cassis de Dijon* and are therefore considered to fall *per se* within the scope of Article 34 TFEU. By contrast, selling arrangements fall within the scope of Article 34 TFEU only under the condition that the party invoking a violation can prove that they introduce discrimination on the basis of the origin of products, either in law or in fact.

<sup>(60)</sup> *Ibid.*, para. 15.

<sup>(61)</sup> *Ibid.*, para. 33.

<sup>(62)</sup> Case C-110/05 *Commission v Italy* [2009] ECLI:EU:C:2009:66.

<sup>(63)</sup> Case C-110/05 *Commission v Italy* [2009] ECLI:EU:C:2009:66, para. 57.

<sup>(64)</sup> Case C-142/05 *Mickelsson and Roos* [2009] ECLI:EU:C:2009:336.

<sup>(65)</sup> Case C-142/05 *Mickelsson and Roos* [2009] ECLI:EU:C:2009:336, para. 28.

<sup>(66)</sup> Case C-142/05 *Mickelsson and Roos* [2009] ECLI:EU:C:2009:336, para. 39-40. To this effect, see also Case C-433/05 *Sandström* [2010] ECLI:EU:C:2010:184.

<sup>(67)</sup> Case C-433/05 *Sandström* [2010] ECLI:EU:C:2010:184, para. 40. This case is also an example of a process-oriented approach to proportionality, built on the Court’s assessment in *Mickelsson*.

<sup>(68)</sup> Joined Cases C-267/91 and C-268/91 *Keck and Mithouard* [1993] ECLI:EU:C:1993:905.

<sup>(69)</sup> Joined Cases C-267/91 and C-268/91 *Keck and Mithouard* [1993] ECLI:EU:C:1993:905, para. 16.

In Case C-591/17 *Republic of Austria*, the Court described selling arrangements as national rules that concern the ‘arrangements under which products may be sold’<sup>(70)</sup>. Accordingly, selling arrangements include measures relating to the conditions and methods of marketing (see Section 4.6),<sup>(71)</sup> the time of the sale of goods<sup>(72)</sup>, the place of the sale of goods or to restrictions regarding by whom goods may be sold<sup>(73)</sup>, as well as in some cases measures which relate to product pricing (see Section 4.4)<sup>(74)</sup>. It is relatively easier to comprehend what types of measures are concerned with the characteristics of the products than what types of measures constitute selling arrangements. Measures which concern the characteristics of a product could be, for example, measures regarding its shape, size, weight, composition, presentation or identification (see Section 4.7).

As an example of the above: the Court held in *Alfa Vita*<sup>(75)</sup> that national legislation, which made the sale of ‘bake-off’ products subject to the same requirements as those applicable to the full manufacturing and marketing procedure for traditional bread and bakery products was in breach of Article 34 TFEU and could not be regarded as a selling arrangement. The Court reached this conclusion on the basis that requiring vendors of ‘bake-off’ products to comply with all of the requirements imposed on traditional bakeries did not take the specific nature of those products into account and entailed additional costs, thereby making the marketing of those products more difficult<sup>(76)</sup>.

Certain procedures or obligations which do not relate to the product or its packaging may be considered as selling arrangements as shown in *Sapod Audic and Eco-Emballages*<sup>(77)</sup>. The national measure at issue provided that any producer or importer was required to contribute to or organise the disposal of all of their packaging waste. The Court pointed out that the measure only imposed ‘a general obligation to identify the packaging collected for disposal by an approved undertaking’<sup>(78)</sup>. Hence, the Court held that the ‘obligation imposed by that provision did not relate as such to the product or its packaging and therefore did not, of itself, constitute a rule laying down requirements to be met by goods, such as requirements concerning their labelling or packaging’<sup>(79)</sup>. As a result, it could be regarded as a selling arrangement.

To recapitulate, selling arrangements are measures which are associated with the marketing of the good rather than with the characteristics of the good<sup>(80)</sup>, and which fall outside the scope of Article 34 TFEU in case they meet the two cumulative conditions established in the *Keck* judgment explained above.

### 3.5. The Mutual Recognition principle

Technical obstacles to the free movement of goods may occur when national authorities apply national rules that lay down requirements to be met by goods lawfully marketed in other Member States. Goods ‘lawfully marketed in another Member State’ are those goods or goods of that type which comply with the relevant rules applicable in that Member State or are not subject to any such rules in that Member State, and are made available to end users in that Member State. If national rules do not implement secondary EU legislation, they constitute technical obstacles to which Articles 34 and 36 TFEU apply, even if those rules apply without distinction to all products.

<sup>(70)</sup> Case C-591/17, *Republic of Austria* [2019] ECLI:EU:C:2019:504, para. 129.

<sup>(71)</sup> See Case C-412/93 *Leclerc-Siplec* [1995] ECLI:EU:C:1995:26, para. 22 and Case C-6/98 *ARD* [1999] ECLI:EU:C:1999:532, para. 46.

<sup>(72)</sup> See, for instance, Cases C-401/92 and C-402/92 *Tankstation 't Heukske and Boermans* [1994] ECLI:EU:C:1994:220, para. 14 and Joined Cases C-69/93 and C-258/93 *Punto Casa* [1994] ECLI:EU:C:1994:226.

<sup>(73)</sup> See Case C-391/92 *Commission v Greece* [1995] ECLI:EU:C:1995:199, para. 15.

<sup>(74)</sup> See Case C-63/94 *Belgacom* [1995] ECLI:EU:C:1995:270 and Case C-221/15 *Etablissements Fr. Colruyt NV* [2016] ECLI:EU:C:2016:704, para. 37.

<sup>(75)</sup> Joined Cases C-158/04 and C-159/04 *Alfa Vita* [2006] ECLI:EU:C:2006:562.

<sup>(76)</sup> *Ibid.*, paras. 18-19.

<sup>(77)</sup> Case C-159/00 *Sapod Audic and Eco-Emballages* [2002] ECLI:EU:C:2002:343.

<sup>(78)</sup> *Ibid.*, para. 71. If it were to be interpreted as imposing an obligation to apply a mark or label, then the measure would constitute a technical regulation within the meaning of Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services (OJ L 204, 21.7.1998, p. 37). In such a case, the individual may invoke the failure to make notification of that national provision. It is then for the national court to refuse to apply that provision.

<sup>(79)</sup> Case C-159/00 *Sapod Audic and Eco-Emballages* [2002] ECLI:EU:C:2002:343, para. 72.

<sup>(80)</sup> See Case C-71/02 *Karner* [2004] ECLI:EU:C:2004:181 (prohibition of reference indicating that goods come from an insolvent estate); Case C-441/04 *A-Punkt* [2006] ECLI:EU:C:2006:141 (door-stepping situation) and also the similar reasoning in Case C-20/03 *Burmanjer* [2005] ECLI:EU:C:2005:307.

The mutual recognition principle was established in the case law of the Court. In the *Cassis de Dijon* judgment <sup>(81)</sup>, the Court established that in the absence of harmonisation, national rules that lay down requirements (such as those relating to designation, form, size, weight, composition, presentation, labelling, packaging) to be met by goods coming from other Member States where they are lawfully manufactured and marketed, represent obstacles to free movement of goods and constitute measures of equivalent effect prohibited by Article 34 TFEU.

According to the mutual recognition principle, if a business is lawfully selling a product in one Member State, in compliance with the applicable national technical rules of that Member State, it should be able to sell it in other Member States without having to adapt it to the national rules of the importing Member State.

Hence, in principle, Member States of destination cannot restrict or deny the placing on the market of goods which are not subject to EU harmonisation and which are lawfully marketed in another Member State, even if they were manufactured according to technical and quality rules different from those that must be met by domestic products. The same applies if there are no technical rules applicable to that product in the Member State of origin.

However, the principle is not absolute: a restriction may be justified by an objective of public interest.

Consequently, mutual recognition should not be viewed as entailing lower health, environment or safety standards, or as limiting the market surveillance capabilities of national authorities, but rather as striking a careful balance between the free movement of goods and the objectives of public interest. Member States must adhere to the principle only if the legitimate public interests covered by their applicable national technical rule are adequately protected.

Exceptions to the free movement of goods are to be interpreted narrowly <sup>(82)</sup>. Barriers are justified only if the national measures are necessary to satisfy mandatory requirements or any of the interests listed in Article 36 TFEU and are proportionate to the legitimate objective pursued. This is summarised well in a recent judgment of the Court, which relates to refusing to recognise certain hallmarks, as follows:

‘Obstacles to the free movement of goods resulting, in the absence of harmonisation of national legislations, from the application by a Member State to goods coming from other Member States, in which they are lawfully manufactured and marketed, of rules relating to conditions with which those goods must comply, even if those rules apply without distinction to all products, therefore constitute measures having equivalent effect prohibited by Article 34 TFEU, unless their application can be justified by an objective of public interest capable of taking precedence over the free movement of goods.’ <sup>(83)</sup>

In the same case, the Court also noted that the principle of mutual recognition cannot apply to trade within the EU in goods originating in third countries and in free circulation where they have not, before being exported to a Member State other than that in which they are in free circulation, been lawfully marketed in the territory of a Member State <sup>(84)</sup>.

Thus, in summary, exceptions from the mutual recognition principle that applies in the non-harmonised area are possible:

- (1) The general rule is that products lawfully marketed in another Member State enjoy the right to free movement, and
- (2) The general rule does not apply if the Member State of destination can prove that it is essential to impose its own technical rules on the products concerned based on the reasons outlined in Article 36 TFEU or in the mandatory requirements developed in the Court’s jurisprudence, subject to the compliance with the principle of proportionality.

<sup>(81)</sup> Case 120/78 *Rewe Zentrale v Bundesmonopolverwaltung für Branntwein* [1979] ECLI:EU:C:1979:42. While at the beginning the principle was not expressly mentioned in the case-law of the Court, it is now fully recognised (see e.g. Case C-110/05 *Commission v Italy* [2009] ECLI:EU:C:2009:66, para. 34 and Case C-385/10 *Elenca* [2012] ECLI:EU:C:2012:634, para. 23).

<sup>(82)</sup> Case C-111/89 *Staat der Nederlanden v P. Bakker Hillegom BV* [1990] ECLI:EU:C:1990:177, para. 8.

<sup>(83)</sup> Case C-525/14 *Commission v Czech Republic* [2016] ECLI:EU:C:2016:714, para. 35.

<sup>(84)</sup> Case C-525/14 *Commission v Czech Republic* [2016] ECLI:EU:C:2016:714, para. 39.

A new Regulation (EU) 2019/515 of the European Parliament and of the Council on the mutual recognition of goods lawfully marketed in another Member State <sup>(85)</sup> applies as of 19 April 2020. It replaces Regulation (EC) No 764/2008 of the European Parliament and of the Council laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State <sup>(86)</sup>.

#### 4. TYPES OF MEASURES

Measures of equivalent effect under Article 34 TFEU take a variety of different forms and shapes. Sometimes they are very blunt measures specifically targeting imports or allowing preferential treatment of domestic goods, and sometimes they are an unexpected side effect of general policy decisions. In past decades, certain types of measures have emerged repeatedly in the jurisprudence and practical application of Articles 34-36 TFEU in infringement procedures. A number of them are described below.

##### 4.1. National provisions related to the act of import (import licences, inspections and controls)

National measures which relate directly to the act of import of products from other Member States can make imports more cumbersome and are therefore regularly considered as measures having equivalent effect to quantitative restrictions contrary to Article 34 TFEU. The obligation to obtain an import licence before importing goods is a clear example in this respect. Because formal processes of this kind can cause delays, even where licences are granted automatically and the Member State concerned does not purport to reserve the right to withhold a licence, such an obligation may infringe Article 34 TFEU <sup>(87)</sup>.

Inspections and controls, such as veterinary, sanitary, phytosanitary and other controls, including customs checks on imports (and exports), are considered to be measures having equivalent effect within the meaning of Articles 34 and 35 respectively <sup>(88)</sup>. Such inspections are likely to make imports or exports more difficult or costly, as a result of the delays inherent in the inspection procedure and the additional transport costs which a trader may thereby incur.

The establishment of the internal market on 1 January 1993 essentially eliminated recurrent border controls for the transfer of goods. Since then, Member States may not carry out controls at their borders unless they are part of a general control system taking place to a similar extent inside the national territory and/or unless they are performed as spot-checks. Irrespective of where such controls take place, however, if they amount to a systematic inspection of imported products, they are still considered as measures of equivalent effect <sup>(89)</sup>. They may only exceptionally be justified, if strict conditions are fulfilled <sup>(90)</sup>.

##### 4.2. Obligations to appoint a representative or to provide storage facilities in the importing Member State

The obligation for an importer to have a place of business in the Member State of destination of goods was found by the Court to directly contravene the Articles on the free movement of goods within the internal market. The Court held that by compelling undertakings established in other Member States to incur the cost of establishing a representative in the Member State of import, this obligation makes it difficult, if not impossible, for certain undertakings, in particular small or medium-sized businesses, to enter that Member State's market <sup>(91)</sup>. An obligation to appoint a representative or agent or set up a secondary establishment, office or storage facility in the importing Member State is generally also contrary to Article 34 TFEU.

<sup>(85)</sup> 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).

<sup>(86)</sup> Regulation (EC) No 764/2008 of the European Parliament and of the Council 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC (OJ L 218, 13.8.2008, p. 21). For details see point 8.3 of this guide.

<sup>(87)</sup> Joined Cases 51-54/71 *Internationale Fruit Company v Produktschap voor Groenten en Fruit* [1971] ECLI:EU:C:1971:128; Case C-54/05 *Commission v Finland* [2007] ECLI:EU:C:2007:168, para. 31.

<sup>(88)</sup> Case 4/75 *Rewe Zentralfinanz v Landwirtschaftskammer* [1975] ECLI:EU:C:1975:98.

<sup>(89)</sup> Case C-272/95 *Dt. Milchkontor II* [1997] ECLI:EU:C:1997:191.

<sup>(90)</sup> Case C-28/09 *Commission v Austria* [2011] ECLI:EU:C:2011:854, para. 119.

<sup>(91)</sup> Case 155/82 *Commission v Belgium* [1983] ECLI:EU:C:1983:53, para. 7.

Some Member States have tried to justify such requirements by arguing that they are necessary to ensure the proper enforcement of national provisions in the public interest, including criminal liability in some cases. The Court has rejected this argument. It held that although each Member State is entitled to take appropriate measures within its territory in order to ensure the protection of public policy, such measures are only justified if certain conditions are met. It must be established that such measures are necessary in order to meet legitimate reasons of general interest and that this cannot be achieved by means which place less of a restriction on the free movement of goods <sup>(92)</sup>. The Court has held that '[e]ven though criminal penalties may have a deterrent effect as regards the conduct which they sanction, that effect is not guaranteed and, in any event, is not strengthened...solely by the presence on national territory of a person who may legally represent the manufacturer' <sup>(93)</sup>. Thus, from the point of view of public interest objectives, the requirement that a representative be established on national territory does not provide sufficient additional safeguards to justify an exception to the prohibition contained in Article 34 TFEU.

National requirements regulating the stocking or storage of imported goods may also amount to a violation of Article 34 TFEU if these measures affect imported goods in a discriminatory manner compared to domestic products. This would include any rules which prohibit, limit or require stocking of imported goods only. A national measure requiring imported wine-based spirits to be stored for at least six months in order to qualify for certain quality designations was held by the Court to constitute a measure having equivalent effect to a quantitative restriction <sup>(94)</sup>.

Similar obstacles to trade in goods may be created by any national rules which totally or partially restrict the use of stocking facilities to domestic products only, or make the stocking of imported products subject to conditions which are different from those required for domestic products and are more difficult to satisfy. Consequently, a national measure encouraging the stocking of domestically produced products could create obstacles to the free movement of goods under Article 34 TFEU.

#### 4.3. National bans on specific products/substances

A ban on the marketing of a specific product or substance is the most restrictive measure a Member State can adopt from the perspective of the free movement of goods. The majority of goods targeted by national bans are foodstuffs, such as vitamins and other food supplements <sup>(95)</sup> and chemical substances <sup>(96)</sup>.

The justifications most often invoked by Member States for these stringent measures are the protection of health and life of humans, animals and plants within Article 36 TFEU, and the mandatory requirements developed in the Court's jurisprudence, such as the protection of the environment. These justificatory grounds are often combined. A Member State imposing a national ban on a product/substance must show that the measure is necessary and, where appropriate, that the marketing of the products in question poses a serious risk to, for example, public health and that those rules are in conformity with the principle of proportionality <sup>(97)</sup>. This includes providing all relevant evidence, such as technical, scientific, statistical or nutritional data <sup>(98)</sup>. In *Humanplasma*, whilst the objective of the restriction was to ensure the quality and safety of blood and blood components, and thus public health, this measure was considered to go beyond what was necessary <sup>(99)</sup>.

Moreover, a Member State bears the burden of proving that the stated aim cannot be achieved by any other means having a less restrictive effect on intra-EU trade <sup>(100)</sup>. For example, in relation to a French ban on the addition to beverages of caffeine above a certain limit, the Court held that 'appropriate labelling, informing consumers about the nature, the ingredients and

<sup>(92)</sup> *Ibid.*, para. 12. See also Case C-12/02 *Grilli* [2003] ECLI:EU:C:2003:538, para. 48 and 49; C-193/94 *Skanavi and Chryssanthakopoulos* [1996] ECLI:EU:C:1996:70, para. 36 to 38.

<sup>(93)</sup> Case 155/82 *Commission v Belgium* [1983] ECLI:EU:C:1983:53, para. 15.

<sup>(94)</sup> Case 13/78 *Eggers v Freie Hansestadt Bremen* [1978] ECLI:EU:C:1978:182.

<sup>(95)</sup> Case 174/82 *Officier van Justitie v Sandoz* [1983] ECLI:EU:C:1983:213; C-24/00 *Commission v France* [2004] ECLI:EU:C:2004:70; C-420/01 *Commission v Italy* [2003] ECLI:EU:C:2003:363; C-192/01 *Commission v Denmark* [2003] ECLI:EU:C:2003:492; C-41/02 *Commission v Netherlands* [2004] ECLI:EU:C:2004:762; C-319/05 *Commission v Germany* [2007] ECLI:EU:C:2007:678.

<sup>(96)</sup> Case C-473/98 *Kemikalieinspektionen v Toolex-Alpha AB* [2000] ECLI:EU:C:2000:379.

<sup>(97)</sup> Case C-421/09 *Humanplasma GmbH v Republic of Austria* [2010] ECLI:EU:C:2010:760, para. 45.

<sup>(98)</sup> Case C-270/02 *Commission v Italy* [2004] ECLI:EU:C:2004:78.

<sup>(99)</sup> Case C-421/09 *Humanplasma GmbH v Republic of Austria* [2010] ECLI:EU:C:2010:760, para. 45.

<sup>(100)</sup> Case 104/75 *De Peijper* [1976] ECLI:EU:C:1976:67.

the characteristics of fortified products, can enable consumers who risk excessive consumption of a nutrient added to those products to decide for themselves whether to use them' <sup>(101)</sup>. Hence, the Court found that the ban on the addition of caffeine above a certain limit was not the least restrictive measure available and therefore not necessary in order to achieve the aim of consumer protection.

The *Danish Vitamins* case <sup>(102)</sup> concerned the Danish administrative practice of prohibiting the enrichment of foodstuffs with vitamins and minerals if it could not be shown that such enrichment met a need of Denmark's population. The Court initially agreed that it was for Denmark itself to decide on its intended level of protection of human health and life, bearing in mind the applicability of the principle of proportionality. The Court remarked, however, that Denmark's authorities had the burden of proof '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' and 'that the marketing of the products in question poses a real risk to public health' <sup>(103)</sup>. Ultimately, the Court concluded that the measure was not justifiable on the basis of a 'real risk to public health', which would have required a detailed assessment on a case-by-case basis of the effects of adding minerals and vitamins to foodstuffs <sup>(104)</sup>.

In general, the Court has taken a restrictive approach to measures of this kind. However, in areas where there is a lack of scientific certainty on the impact of a specific product or substance on public health or the environment, for example, it has proven more difficult for the Court to reject such bans <sup>(105)</sup>. In these cases, the so-called precautionary principle also plays an important role in the Court's overall assessment of the case <sup>(106)</sup>.

Situations may also arise in cases concerning the protection of public health where Member States do not ban the addition of a product or substance authorised in another Member State outright, but simply require a prior authorisation for its addition. In these instances, Member States will only comply with their obligations under EU law if such procedures are accessible and can be completed within a reasonable time-frame and if the banning of a product can be challenged before national courts. This procedure must be expressly provided for in a measure of general application which is binding on the national authorities of the Member State. The characteristics of this 'simplified procedure' were established by the Court in Case C-344/90 <sup>(107)</sup>.

#### 4.4. Price measures

Although the Treaty does not contain specific provisions with regard to national regulations on price controls, the Court has on several occasions applied Article 34 TFEU to national price control regulations.

Such regulations cover a number of measures: minimum and maximum prices, price freezes, minimum and maximum profit margins and resale price maintenance.

*Minimum prices:* A minimum price fixed at a specific amount, although applicable without distinction to domestic and imported products, can restrict imports by preventing their lower cost price from being reflected in the retail selling price. This impedes importers from using their competitive advantage and thus is a measure having equivalent effect within Article 34 TFEU, as the consumer cannot take advantage of this price <sup>(108)</sup>. Minimum prices may however be regulated at EU level, as for example, with national legislation setting minimum prices for tobacco, which should be considered in the light of Council Directive 2011/64/EU of 21 June 2011 on the structure and rates of excise duty applied to manufactured tobacco <sup>(109)</sup>.

In Case C-221/15 *Colruyt*, which concerned the pricing of tobacco products in Belgium, the Court held that national legislation prohibiting retailers from selling tobacco products at a unit price lower than the price indicated by the manufacturer or importer affixed on the product, in so far as that price was freely determined by the latter, is not

<sup>(101)</sup> Case C-24/00 *Commission v France* [2004] ECLI:EU:C:2004:70, para. 75.

<sup>(102)</sup> Case C-192/01 *Commission v Denmark* [2003] ECLI:EU:C:2003:492.

<sup>(103)</sup> Case C-192/01 *Commission v Denmark* [2003] ECLI:EU:C:2003:492, para. 46.

<sup>(104)</sup> *Ibid.*, para. 56.

<sup>(105)</sup> Case C-473/98 *Kemikalieinspektionen v Toolex-Alpha AB* [2000] ECLI:EU:C:2000:379; Case C-24/00 *Commission v France* [2004] ECLI:EU:C:2004:70.

<sup>(106)</sup> See further, point 7.1.2.

<sup>(107)</sup> Case C-344/90 *Commission v France* [1992] ECLI:EU:C:1992:328.

<sup>(108)</sup> Case 231/83 *Cullet* [1985] ECLI:EU:C:1985:29; Case 82/77 *Van Tiggele* [1978] ECLI:EU:C:1978:10.

<sup>(109)</sup> OJ L 176, 5.7.2011, p. 24.

precluded under Article 34 TFEU <sup>(110)</sup>. Here, the Court found minimum tobacco product pricing to constitute a certain selling arrangement which applies to all relevant traders operating within the national territory and which does not impede access to the Belgian market of tobacco products from another Member State any more than it impedes the access of domestic tobacco products.

In *Scottish Whiskey Association*, the Court considered whether the Scottish government had breached Article 34 TFEU by imposing minimum prices per unit of alcohol. The measures were intended to eliminate very low-priced alcohol from the market and sought to be justified for reasons of public health. The Court found that the fact that the national legislation 'prevented the lower cost price of imported products being reflected in the selling price to the consumer' constituted a measure having equivalent effect <sup>(111)</sup>.

*Maximum prices*: Prior to *Keck*, the Court held that although a maximum price which is applicable without distinction to domestic products and imported products does not in itself constitute a measure having equivalent effect to a quantitative restriction, it may have such an effect if it is fixed at a level which makes the sale of the imported product either impossible or more difficult than that of its domestic counterpart. It may remove any competitive advantage of imported goods and/or, if the maximum price is set too low, it may not take into account the costs of transport borne by an importer <sup>(112)</sup>.

*Price freezes*: Similarly, prior to the *Keck* ruling (see Section 3.4.2.2), the Court considered in its early jurisprudence that price freezes which are applicable equally to national products and to imported products do not per se amount to a measure having an equivalent effect to a quantitative restriction. However, they may produce such an effect *de facto* if prices are fixed at such a level that the marketing of imported products becomes either impossible or more difficult than the marketing of domestic products <sup>(113)</sup>. This will be the case if importers can market imported products only at a loss.

*Minimum and maximum profit margins*: These are margins which are set at a specific amount rather than as a percentage of the cost price. According to the EU Court's case law prior to *Keck*, these would not necessarily constitute a measure of equivalent effect within the meaning of Article 34 TFEU. The same would apply to a fixed retail profit margin, which is a proportion of the retail price freely determined by the manufacturer, at least when it constitutes adequate remuneration for the retailer. However, a maximum profit margin which is fixed at a single amount applicable both to domestic products and imports but which fails to make allowance for the cost of importation is caught by Article 34 TFEU <sup>(114)</sup>.

Since *Keck*, it appears that the Court has often considered national price control regulations to come within the concept of 'selling arrangements' <sup>(115)</sup>. In this respect, they may fall outside the scope of Article 34 TFEU if certain conditions are met. The fact that 'price controls' may constitute 'selling arrangements' is confirmed in the *Belgapom* case, where the Belgian legislation prohibiting sales at a loss and sales yielding only a very low profit margin was held to fall outside the scope of Article 34 TFEU <sup>(116)</sup>.

In the more recent *LIBRO* case, however, the Court initially classified a rule prohibiting importers of German-language books from fixing a price lower than the retail price fixed/recommended by the publisher as a certain selling arrangement as defined in *Keck*. However, it concluded that the rule was in fact a measure having equivalent effect, in so far as it created a distinct regulation which treated products from other Member States less favourably <sup>(117)</sup>.

In *Deutsche Parkinson Vereinigung*, the Court applied the market access approach in its examination of a price-fixing system for the sale of prescription-only medicinal products for human use by pharmacies, without directly referring to *Keck* in its judgment. After comparing the impact of price fixing on pharmacies established in Germany and in other Member States,

<sup>(110)</sup> Case C-221/15 *Colruyt* [2016] ECLI:EU:C:2016:704, para. 41.

<sup>(111)</sup> Case C-333/14 *Scottish Whiskey Association and Others v The Lord Advocate and The Advocate General of Scotland* [2015] ECLI:EU:C:2015:845, para. 50.

<sup>(112)</sup> Case 65/75 *Tasca* [1976] ECLI:EU:C:1976:30; Case 88-90/75 *SADAM* [1976] ECLI:EU:C:1976:32; Case 181/82 *Roussel* [1983] ECLI:EU:C:1983:352; Case 13/77 *GB-INNO v ATAB* [1977] ECLI:EU:C:1977:185.

<sup>(113)</sup> Case 16-20/79 *Danis* [1979] ECLI:EU:C:1979:248.

<sup>(114)</sup> Case 116/84 *Roelstrate* [1985] ECLI:EU:C:1985:237; Case 188/86 *Lefevre* [1987] ECLI:EU:C:1987:327.

<sup>(115)</sup> For additional information concerning selling arrangements see Section 3.4.2.2.

<sup>(116)</sup> Case C-63/94 *Belgapom v ITM and Vocarex* [1995] ECLI:EU:C:1995:270.

<sup>(117)</sup> Case C-531/07 *Fachverband der Buch- und Medienwirtschaft v LIBRO* [2009] ECLI:EU:C:2009:276.



it ultimately found this system to be a measure having equivalent effect to a quantitative restriction on imports <sup>(118)</sup>. Mail-order pharmacies were found to have a limited ability to compete with traditional pharmacies in terms of services, and therefore primarily competed on the basis of prices, and as a result, were more affected by price fixing. In its assessment, the Court referred to the *DocMorris* case, concerning German legislation prohibiting the sale of medicinal products outside of pharmacies and thus online, which applied *Keck* in its reasoning <sup>(119)</sup>.

As outlined above, in *Scottish Whiskey Association*, the Court concluded that minimum pricing constituted a measure having equivalent effect on the basis of the market access test, without referring to *Keck* expressly. It reasoned that ‘the fact that the legislation at issue... prevents the lower cost price of imported products being reflected in the selling price to the consumer means, by itself, that that legislation is capable of hinder the access’ <sup>(120)</sup>.

#### 4.5. Authorisation procedures

National systems which subject the marketing of goods to prior authorisation restrict access to the market of the importing Member State and are therefore regarded as creating a measure having an effect equivalent to a quantitative restriction within the meaning of Article 34 TFEU <sup>(121)</sup>. The Court of Justice has set a number of conditions under which such prior authorisation might be justified <sup>(122)</sup>:

- It must be based on objective, non-discriminatory criteria which are known in advance to the undertakings concerned, in such a way as to circumscribe the exercise of the national authorities’ discretion, so that it is not used arbitrarily,
- It should not essentially duplicate controls which have already been carried out in the context of other procedures, either in the same or another Member State,
- A prior authorisation procedure will only be necessary where subsequent control must be regarded as being too late to be genuinely effective and enable it to achieve the aim pursued,
- The procedure should not, on account of its duration or the disproportionate costs it entails, be such as to deter the operators concerned from pursuing their business plan,
- The procedure may not require technical analyses where these have already been carried out in another Member State and those results are available <sup>(123)</sup>.

##### 4.5.1. Type approval

Type approval requirements predefine the regulatory, technical and safety conditions a product must fulfil. Accordingly, type approval is not confined to a particular industry, as such requirements exist for products as diverse as marine equipment, mobile phones, passenger cars and medical equipment.

Generally, type approval is required before a product may be placed on the market. Compliance with type-approval requirements is often denoted by a marking on the product. The CE marking, for example, confirms compliance with such requirements by means of either a manufacturer’s self-declaration or third-party certification.

Whilst common EU-wide type-approval requirements normally facilitate the marketing of products in the internal market, national type approval in non-harmonised areas may create barriers to trade of goods. In addition, diverging national product standards make it difficult for manufacturers to market the same product in different Member States and may well lead to higher compliance costs. Obligations requiring national type approval prior to the placing of products on the market are therefore to be seen as measures having equivalent effect <sup>(124)</sup>.

<sup>(118)</sup> Case C-148/15 *Deutsche Parkinson Vereinigung* [2016] ECLI:EU:C:2016:776, paras. 23-27.

<sup>(119)</sup> Case C-322/01 *DocMorris* [2003] ECLI:EU:C:2003:664, para. 6

<sup>(120)</sup> Case C-333/14 *Scottish Whiskey Association* [2015] ECLI:EU:C:2015:845, para. 32. (emphasis added)

<sup>(121)</sup> See for instance Case C-254/05 *Commission v Belgium* [2007] ECLI:EU:C:2007:319; Case C-432/03 *Commission v Portugal* [2005] ECLI:EU:C:2005:669, para. 41; Case C-249/07 *Commission v Netherlands* [2008] ECLI:EU:C:2008:683, para. 26.

<sup>(122)</sup> Case C-390/99 *Canal Satélite Digital* [2002] ECLI:EU:C:2002:34; Case C-333/08 *Commission v France* [2010] ECLI:EU:C:2010:44; Case C-423/13 *Vilniaus Energija* [2014] ECLI:EU:C:2014:2186.

<sup>(123)</sup> Case C-423/13 *Vilniaus Energija* [2014] ECLI:EU:C:2014:2186, para. 55.

<sup>(124)</sup> Case 21/84 *Commission v France* [1985] ECLI:EU:C:1985:184.

On the basis of health or safety justifications, a Member State may be entitled to require a product which has already received approval in another Member State to undergo a fresh procedure of examination and approval. However, in such cases the importing Member State must take account of tests or controls carried out in the exporting Member State(s) which provide equivalent guarantees or protection <sup>(125)</sup>.

In *Commission v Portugal* <sup>(126)</sup> an undertaking was refused the required authorisation by the supervising body for the installation of imported polyethylene pipes, on the grounds that such pipes had not been approved by the national testing body. The certificates of the undertaking which were not recognised had been issued by an Italian testing institute. The Court held that authorities, in this case those of Portugal, are required to take account of certificates issued by the certification bodies of another Member State, especially if those bodies are authorised by the Member State for this purpose. In so far as the Portuguese authorities did not have sufficient information to verify the certificates in question, they could have obtained that material from the authorities of the exporting Member State. A pro-active approach on the part of the national body to which an application is made for approval or recognition of a product is required.

#### 4.5.2. Car registration

Generally, there are three different steps in the process of obtaining a registration for a motor vehicle, according to EU legislation. First, the technical characteristics of the motor vehicle must be approved, in most cases by the EC type-approval. Some types of motor vehicles, however, are still subject to national approval procedures. Second, roadworthiness testing of used vehicles is conducted, the objective of which is to verify that the specific motor vehicle is in a good state of repair at the time of registration. Finally, the motor vehicle is registered, which authorises its entry into service in road traffic, identifies the motor vehicle concerned and issues a registration number to it.

The Court has also dealt with the refusal to register a vehicle which has its steering equipment, including the position of the steering-wheel, on the right-hand side. It held in Cases C-61/12 and C-639/11 that such a legislation constitutes a measure having equivalent effect to quantitative restrictions on imports, as far as its effect is to hinder access to the market for vehicles with steering equipment on the right, which are lawfully constructed and registered in another Member State. The Court stated that such a requirement was not necessary to achieve the objective of road safety <sup>(127)</sup>.

#### 4.6. Advertising restrictions

The role of advertising is primordial in entering the market, especially for products lawfully marketed in another Member State. The important role of advertising in enabling a product from one Member State to penetrate a new market in another Member State has been recognised by Advocates General <sup>(128)</sup> and the Court of Justice <sup>(129)</sup>. The aim and effect of advertising is to, among others, persuade consumers to switch brands or buy new products.

Before *Keck* (see Section 3.4.2.2), the Court often held that national measures imposing advertising restrictions were covered by Article 34 TFEU. One such case was *Oosthoek*, concerning a ban on offering or giving free gifts for sales promotion purposes. The Court held that 'legislation which restricts or prohibits certain forms of advertising and certain means of sales promotion may, although it does not directly affect imports, be such as to restrict their volume because it affects marketing opportunities for the imported products.' <sup>(130)</sup> Since *Keck*, however, the Court has in some respects appeared to adopt a different approach (treating advertising restrictions as selling arrangements). Regardless, measures relating to advertising which appear to fall into the category of selling arrangements are treated as rules relating to products where it appears that they affect the conditions which the goods must meet <sup>(131)</sup>.

<sup>(125)</sup> Case C-455/01 *Commission v Italy* [2003] ECLI:EU:C:2003:551.

<sup>(126)</sup> Case C-432/03 *Commission v Portugal* [2005] ECLI:EU:C:2005:514.

<sup>(127)</sup> Case C-61/12 *Commission v Lithuania* [2014] ECLI:EU:C:2014:172, paras. 57 and 69. See also Case C-639/11 *Commission v Poland* [2014] ECLI:EU:C:2014:173.

<sup>(128)</sup> See for example Advocate General Jacobs in Case C-412/93 *Leclerc-Siplec* [1995] ECLI:EU:C:1995:26 and Advocate General Geelhoed in Case C-239/02 *Douwe Egberts* [2004] ECLI:EU:C:2004:445.

<sup>(129)</sup> See for example joined Cases C-34/95 and C-36/95 *De Agostini* [1997] ECLI:EU:C:1997:344.

<sup>(130)</sup> Case 286/81 *Oosthoek* [1982] ECLI:EU:C:1982:438, para. 15. See also pre-*Keck* cases: Case 362/88 *GB-INNO* [1990] ECLI:EU:C:1990:102 and Case C-1/90 *Aragonesa* [1991] ECLI:EU:C:1991:327.

<sup>(131)</sup> Case C-470/93 *Mars* [1995] ECLI:EU:C:1995:224, para. 13 (measure requires additional packaging and advertising costs). See also Case C-368/95 *Familiapress* [1997] ECLI:EU:C:1997:325, para. 11.

Hence, the usual approach followed by the Court today seems to be that restrictions on advertising and promotion are to be considered as selling arrangements and, if non-discriminatory, falling outside the scope of Article 34 TFEU <sup>(132)</sup>. However, if the measure concerned is discriminatory, it is caught under Article 34 TFEU. National advertising restrictions which render the sale of goods from other Member States more difficult than the sale of domestic goods may therefore constitute a measure of equivalent effect to a quantitative restriction. The Court has held for example that an ‘absolute prohibition of advertising the characteristics of a product’ <sup>(133)</sup> could impede market access of products from other Member States more than it impedes access by domestic products, with which the consumers are more familiar <sup>(134)</sup>.

As seen above, the Court seems to link the scope of the restriction with discrimination. In other words, if the restriction is total, it is presumed that it could have a greater impact on imported products <sup>(135)</sup> and, if partial, that it could be affecting domestic and imported products in the same way <sup>(136)</sup>. However, it should be stressed that the Court in *Dior* <sup>(137)</sup> and *Gourmet* <sup>(138)</sup> indicated that some *advertising bans* might not necessarily affect imports more strongly than national goods.

The Court has also underlined that restrictions on internet advertising do not affect the sale of national goods, in this case, national medicinal products, in the same way as it affects the sale of medicinal products originating in other Member States (Case C-322/01 *Deutscher Apothekerverband*). Therefore, restrictions on internet advertising may represent an obstacle covered by Article 34 TFEU.

#### 4.7. **Technical regulations containing requirements as to the presentation of goods (weight, composition, presentation, labelling, form, size, packaging)**

Requirements to be met by imported products in regard to shape, size, weight composition, presentation, identification or putting up may force manufacturers and importers to adapt the products in question to the rules in force in the Member State in which they are marketed, for example by altering the labelling of imported products <sup>(139)</sup>. In its judgment in Case 27/80 *Fietje* <sup>(140)</sup> the Court of Justice held that the extension by a Member State of a provision which prohibits the sale of certain alcoholic beverages under a description other than that prescribed by national law to beverages imported from other Member States, thereby making it necessary to alter the label under which the imported beverage is lawfully marketed in the exporting Member state, is to be considered a measure having an effect equivalent to a quantitative restriction, which is prohibited by Article 34 TFEU.

Given that requirements as to the presentation of goods are directly interlinked with the product itself, they are not considered to be selling arrangements. Rather, these are considered measures having equivalent effect within Article 34 TFEU <sup>(141)</sup>.

The following measures, for example, have been deemed contrary to Article 34 TFEU:

- A strict requirement for non-harmonised construction products to be affixed with a CE mark <sup>(142)</sup>,
- A requirement for margarine to be sold in cubic packaging to distinguish it from butter <sup>(143)</sup>,

<sup>(132)</sup> See Case C-292/92 *Hünermund* [1993] ECLI:EU:C:1993:932 (ban on advertising ‘parapharmaceutical’ products outside the confines of pharmacies) and Case C-412/93 *Leclerc-Siplec* [1995] ECLI:EU:C:1995:26 (restriction of television advertising); Cf. Joined Cases C-34/95 and C-36/95 *De Agostini* [1997] ECLI:EU:C:1997:344; Case C-405/98 *Gourmet* [2001] ECLI:EU:C:2001:135.

<sup>(133)</sup> Case C-239/02 *Douwe Egberts* [2004] ECLI:EU:C:2004:445, para. 53.

<sup>(134)</sup> As to discrimination between the domestic economic operators and other Member States’ economic operators see Case C-322/01 *DocMorris* [2003] ECLI:EU:C:2003:664, para. 74 and Case C-254/98 *Heimdienst* [2000] ECLI:EU:C:2000:12, para. 26. See also Cases 87/85 and 88/85 *Legia and Gyselinx* [1986] ECLI:EU:C:1986:215, para. 15 and Case C-189/95 *Franzén* [1997] ECLI:EU:C:1997:504, para. 71.

<sup>(135)</sup> In this context, see Case C-405/98 *Gourmet* [2001] ECLI:EU:C:2001:135; Cases C-34/95 and C-36/95 *De Agostini* [1997] ECLI:EU:C:1997:344 and Case C-239/02 *Douwe Egberts* [2004] ECLI:EU:C:2004:445 (prohibiting references to ‘slimming’ and ‘medical recommendations, attestations, declarations or statements of approval’).

<sup>(136)</sup> In this context, see Case C-292/92 *Hünermund* [1993] ECLI:EU:C:1993:932 and Case C-71/02 *Karner* [2004] ECLI:EU:C:2004:181 (prohibiting references to the fact that goods come from an insolvent estate).

<sup>(137)</sup> Case C-337/95 *Dior* [1997] ECLI:EU:C:1997:517.

<sup>(138)</sup> Case C-405/98 *Gourmet* [2001] ECLI:EU:C:2001:135.

<sup>(139)</sup> Case C-33/97 *Colim* [1999] ECLI:EU:C:1999:274, para. 37 and Case C-416/00 *Morellato* [2003] ECLI:EU:C:2003:475, para. 29 and 30; Case C-217/99 *Commission v Belgium* [2000] ECLI:EU:C:2000:638, para. 17.

<sup>(140)</sup> Case 27/80 *Fietje* ECLI:EU:C:1980:293, para.15.

<sup>(141)</sup> Case C-385/10 *Elenca Srl v Ministero dell’Interno* [2012] ECLI:EU:C:2012:634.

<sup>(142)</sup> *Ibid.*

<sup>(143)</sup> Case 261/81 *Rau v De Smedt* [1982] ECLI:EU:C:1982:382.

- A prohibition by a Member State on marketing of articles made from precious metals without the requisite (official national) hallmarks <sup>(144)</sup>,
- A prohibition on marketing of videos and DVDs sold through mail orders and online sales which do not bear an age-limit label corresponding to a classification decision from a higher regional authority or a national self-regulation body <sup>(145)</sup>.

#### 4.8. Indications of origin, quality marks, incitement to buy national products

National rules requiring the indication of the origin of the product on the product or its labelling constitute a measure of equivalent effect contrary to Article 34 TFEU.

The Court has ruled that national rules on the mandatory indication of origin may encourage consumers to buy national products to the detriment of equivalent products originating in other Member States <sup>(146)</sup>. Such rules, according to the Court, have the effect of making the marketing in a Member State of similar goods produced in other Member States more difficult, and slow down economic interpenetration in the European Union by handicapping the sale of goods produced as the result of a division of labour between Member States <sup>(147)</sup>. The Court has also pointed out that it could be in the economic operator's interest to indicate himself the origin of his products, without being compelled to do so. In this case, consumers can be protected against false or misleading indications of origin that could arise by relying on existing rules prohibiting such behaviour <sup>(148)</sup>.

The Court has likewise held that quality schemes laid down in national law and related to the origin of the product may have a similar effect. Even if such a particular quality scheme is voluntary, it does not cease to be a measure of equivalent effect, if the use of that designation promotes or is likely to promote the marketing of the product concerned as compared with products which do not benefit from its use <sup>(149)</sup>.

The Court has held that Member States are empowered to lay down quality schemes for agricultural products marketed on their territory and may make the use of designations of quality subject to compliance with such schemes. However, such schemes and designations may not be linked to a requirement that the production process for the products in question be carried on within the country but should be dependent solely on the existence of the intrinsic objective characteristics which give the products the quality required by law <sup>(150)</sup>. Such scheme must therefore be accessible to any producer in the Union or any other potential Union operator whose products meet the requirements. Any requirement that impedes the accessibility to this scheme for products from other Member States should be avoided as it is liable to facilitate the marketing of products of domestic origin to the detriment of imported products <sup>(151)</sup>.

The Court accepted quality schemes laid down in national law when these allow for the importation of products from other Member States under the designations they bear, even if they are similar, comparable or identical to the designations provided for in the national legislation <sup>(152)</sup>.

A promotional campaign run by Member States' authorities and involving quality or/and origin labelling equally constitute a measure of equivalent effect under Article 34 TFEU. The most famous case of such an incitement to buy national products was the *Buy Irish* case <sup>(153)</sup>, which involved a large-scale campaign encouraging the purchase of national goods. The Court has also held that a scheme set up by authorities in order to promote the distribution of some products made in a certain country or region, may likewise encourage consumers to buy such products to the exclusion of imported products <sup>(154)</sup>.

<sup>(144)</sup> Case C-30/99 *Commission v Ireland* [2001] ECLI:EU:C:2001:346; Case C-525/14 *Commission v Czech Republic* [2016] ECLI:EU:C:2016:714; See also Case C-481/12 *UAB Juvelta v VĮ Lietuvos prabavimo rūmai* [2014] ECLI:EU:C:2014:11.

<sup>(145)</sup> Case C-244/06 *Dynamic Medien Vertriebs GmbH v Avides Media AG* [2008] ECLI:EU:C:2008:85, in this judgment the trade barrier was however considered justified for reasons of the protection of minors.

<sup>(146)</sup> See, for instance, Case 207/83 *Commission v United Kingdom* [1985] ECLI:EU:C:1985:161, para 17.

<sup>(147)</sup> See Case C-95/14 *UNIC and Uni.co.pel* [2015] ECLI:EU:C:2015:492, para. 44.

<sup>(148)</sup> See Case 207/83 *Commission v United Kingdom* [1985] ECLI:EU:C:1985:161, para 21.

<sup>(149)</sup> See Case C-325/00 *Commission v Germany* [2002] ECLI:EU:C:2002:633, para. 24 and Case C-255/03 *Commission v Belgium* ECLI:EU:C:2004:378.

<sup>(150)</sup> See Case 13/78 *Eggers* ECLI:EU:C:1978:182, paras. 24-25.

<sup>(151)</sup> See the judgment of the Court in Joined Cases C-321/94 to C-324/94 *Pistre and others*, ECLI:EU:C:1997:229, para. 45.

<sup>(152)</sup> Case C-169/17 *Asociación Nacional de Productores de Ganado Porcino* [2018] ECLI:EU:C:2018:440, para. 24-28 and case-law cited.

<sup>(153)</sup> Case 249/81 *Commission v Ireland* [1982] ECLI:EU:C:1982:402.

<sup>(154)</sup> See, for instance, Case C-325/00 *Commission v Germany* [2002] ECLI:EU:C:2002:633, Case C-6/02 *Commission v France* [2003] ECLI:EU:C:2003:136. See also Joined Cases C-204/12 to C-208/12 *Essent Belgium* [2014] ECLI:EU:C:2014:2192 paras. 88, 90-95 and 116. See also C-573/12 *Ålands Vindkraft* [2014] ECLI:EU:C:2014:2037.

#### 4.9. Restrictions on distance selling (internet sales, mail order, etc.)

With the advancement of information and communication technologies, goods are increasingly traded within the internal market via the internet. Thus, the number of cases linked to internet transactions involving the transfer of goods from one Member State to another put forward in front of the Court of Justice has increased.

The questions referred to the Court in *DocMorris* <sup>(155)</sup> arose in national proceedings concerning internet sales of medicinal products for human use in a Member State other than that in which *DocMorris* was established. German law at the time prohibited the sale by mail order of medicinal products which may only be sold in pharmacies.

The first question referred by the national court was whether there is a breach of Article 34 TFEU in the event that authorised medicinal products, the sale of which is restricted to pharmacies in the Member State concerned, may not be imported commercially by mail order through pharmacies approved in other Member States in response to an individual order over the internet.

The Court started by treating this national restriction as a selling arrangement, which may be in breach of Article 34 if it is discriminatory. First, along the lines of *De Agostini* (re: the importance of advertisement to the sale of the product in question) <sup>(156)</sup>, the Court emphasised the importance of the internet to the sale of a product. Then it explained how such an outright ban is more of an obstacle to pharmacies outside Germany than those within it. Hence the measure was in breach of Article 34 TFEU.

More specifically, the Court held that for pharmacies not established in Germany, the internet provides a more significant way to gain 'direct access' to the German market <sup>(157)</sup>. The Court explained that a prohibition which has a greater impact on pharmacies established outside Germany could impede access to the market for products from other Member States more than it impedes access for domestic products.

In *Ker-Optika* <sup>(158)</sup>, which concerned national legislation authorising the sale of contact lenses solely in medical supply shops, the Court confirmed that by prohibiting its sales online, the national measure breached Directive 2000/31/EC of the European Parliament and of the Council <sup>(159)</sup> and Articles 34-36 TFEU for the prohibition of the subsequent delivery of the contact lenses to customers.

A more recent *Visnapuu* judgment related to the Finnish Alcohol Act, under which a seller established in another Member State must hold a retail sale licence in order to import alcoholic beverages with a view to sell these beverages at retail to consumers residing in Finland. The Court held that the requirement to hold a retail sale licence in order to import alcoholic beverages prevents traders established in other Member States from freely importing alcoholic beverages into Finland, and thus constitutes a measure having equivalent effect to a quantitative restriction on imports within the meaning of Article 34 TFEU. However, it also held that Articles 34 TFEU and 36 TFEU do not preclude such legislation, provided that it is appropriate for securing the attainment of the objective of protection of health and public policy <sup>(160)</sup>.

#### 4.10. Deposit obligations

Deposit and return systems, especially in the beverages sector, have given rise to discussions in the light of environmental legislation and internal market rules in the past decades. For operators engaged in several Member States, such systems often make it difficult to sell the same product in the same packaging in different Member States. Instead, producers and

<sup>(155)</sup> Case C-322/01 *DocMorris* [2003] ECLI:EU:C:2003:664.

<sup>(156)</sup> Joined Cases C-34/95 and C-36/95 *De Agostini* [1997] ECLI:EU:C:1997:344, paras. 43-44. Advocate General Geelhoed (Case C-239/02 *Douwe Egberts* [2004] ECLI:EU:C:2004:445, para. 68) contrasts this reasoning with the reasoning of the Court in C-292/92 *Hünermund* ([1993] ECLI:EU:C:1993:932) and C-412/93 *Leclerc-Siplec* ([1995] ECLI:EU:C:1995:26). He argued that the advertising prohibitions in the last two cases were limited in scale. He pointed out that the Court in the last two cases attached importance to the fact that the restrictions in question did not affect the opportunities for other traders to advertise the products concerned by other means. In other words, 'the function which advertising performed in relation to gaining access to the market for the products concerned remained intact.'

<sup>(157)</sup> Case C-322/01 *DocMorris* [2003] ECLI:EU:C:2003:664, para. 74.

<sup>(158)</sup> Case C-108/09 *Ker-Optika* [2010] ECLI:EU:C:2010:725, paras. 43-44.

<sup>(159)</sup> Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market ('Directive on electronic commerce') (OJ L 178, 17.7.2000, p. 1).

<sup>(160)</sup> Case C-198/14 *Visnapuu* [2015] ECLI:EU:C:2015:751, paras. 99, 102, 208 and 129.

importers are required to adapt the packaging to the needs of each individual Member State, which usually leads to additional costs. The effect of such systems, i.e. the partition of markets, often runs counter to the idea of a truly internal market. Therefore, national requirements in this sense may be considered as a barrier to trade under Article 34 TFEU. Regardless, deposit schemes may be justified by reasons relating to protection of the environment.

In two judgments concerning the German mandatory deposit system for non-reusable beverage packaging in the early 2000s, the Court confirmed that as EU law stands, Member States are entitled to choose between a deposit-and-return system, a global packaging-collection system or a combination of the two systems <sup>(161)</sup>.

Today, deposit schemes are partly covered by harmonisation legislation, i.e. European Parliament and of the Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste <sup>(162)</sup>. However, as of 2020, there is no Union-wide deposit scheme in place. When a national provision is outside the scope of the relevant directives, its compatibility with Articles 34-36 TFEU has to be assessed.

#### 4.11. Reimbursement and parallel imports

*Reimbursement:* EU law does not detract from the power of the Member States to organise their social security systems <sup>(163)</sup>; in the absence of harmonisation at EU level, the laws of each Member State determine the circumstances in which social security benefits are granted. However, those laws may affect marketing possibilities and in turn may influence the scope for importation. It follows that a national decision on reimbursement of pharmaceuticals may have a negative impact on their importation.

Furthermore, it follows from the *Duphar* judgment that provisions of national legislation governing the reimbursement of medical devices within the framework of the national health-care scheme may be compatible with Article 34 TFEU, provided certain conditions are met. The determination of the products subject to reimbursement and those which are excluded may not involve discrimination regarding the origin of the products and must be carried out on the basis of objective and verifiable criteria. It should, moreover, be possible to amend the list of reimbursed products whenever compliance with the specified criteria so requires. The ‘objective and verifiable criteria’ referred to by the Court may concern the existence on the market of other, less expensive products having the same therapeutic effect, the fact that the items in question are freely marketed without the need for any medical prescription, or the fact that products are excluded from reimbursement for reasons of a pharmaco-therapeutic nature justified by the protection of public health.

Procedural rules for establishing national reimbursement decisions were specified by Council Directive 89/105/EEC relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems <sup>(164)</sup>.

In *Decker* <sup>(165)</sup>, the Court found that national rules under which reimbursement of the cost of medical products is subject to prior authorisation by the competent institution of a Member State when products are purchased in another Member State, constitute a restriction on the free movement of goods within the meaning of Article 34 TFEU. In this case, since they encourage insured persons to purchase those products in their home Member State rather than in another Member State, and are thus liable to curb the import of products in other Member States.

<sup>(161)</sup> Case C-463/01 *Commission v Germany* [2004] ECLI:EU:C:2004:797; Case C-309/02 *Radlberger Spitz* [2004] ECLI:EU:C:2004:799.

<sup>(162)</sup> OJ L 365, 31.12.1994, p. 10.

<sup>(163)</sup> See Case 238/82 *Duphar* [1984] ECLI:EU:C:1984:45 and Case C-70/95 *Sodemare and Others* [1997] ECLI:EU:C:1997:301.

<sup>(164)</sup> Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems (OJ L 40, 11.2.1989, p. 8).

<sup>(165)</sup> Case C-120/95 *Decker* [1998] ECLI:EU:C:1998:167.

*Parallel imports*: Parallel trade in products is a lawful form of trade within the internal market. It is 'parallel' in the sense that it involves products that are of the same description but from a different batch to products marketed through manufacturers' or original suppliers' distribution networks, but takes place outside (often alongside) those networks. Parallel trade comes about as a result of price divergence of pharmaceuticals<sup>(166)</sup> or pesticides<sup>(167)</sup>, e.g. when Member States set or by other means control the price of products sold within their respective markets. Parallel trade creates in principle healthy competition and price reductions for consumers and is a direct consequence of the development of the internal market, which guarantees the free movement of goods and prevents the compartmentalisation of national markets<sup>(168)</sup>.

Although the safety and initial marketing of medicinal products are regulated by EU legislation, the principles surrounding the legality of parallel trade in these products have emerged from judgments of the Court based on the Treaty provisions on the free movement of goods<sup>(169)</sup>.

Parallel importers cannot be required to satisfy the same requirements as those applicable to economic operators applying for the first time for a marketing authorisation, provided that the protection of human health is not undermined<sup>(170)</sup>. When the information necessary for the purposes of public health protection is already available to the competent authorities of the Member State of destination as a result of the first marketing of a product in this Member State, a parallel imported product is subject to a licence granted on the basis of a proportionally 'simplified' procedure (compared to a marketing authorisation procedure), provided:

- **The imported product has been granted a marketing authorisation in the Member State of origin**, and regardless of the expiration of that marketing authorisation, in particular when the reference authorisation expires for reasons other than the protection of public health, i.e. solely based on the wish of the holder of the reference authorisation<sup>(171)</sup>, and
- **The imported product is essentially similar to a product that has already received marketing authorisation in the Member State of destination**, meaning that the two products do not have to be identical in all respects but they should have at least been manufactured according to the same formulation, using the same active ingredient, and that they also have the same therapeutic effects<sup>(172)</sup>. Thus, a refusal to issue a marketing authorisation cannot be justified on grounds of protecting public health if that refusal is based solely on the fact that the two medicinal products do not have the same origin<sup>(173)</sup>.

Additionally, national authorities cannot refuse granting a parallel import licence solely on grounds linked to the absence of documentation related to the medicinal product subject to parallel import, if they have available legislative and administrative means to obtain the documentation in question<sup>(174)</sup>. Nor can they refuse, in the case of veterinary medicinal products, a parallel import licence for those wishing to import for use on their own stock farm<sup>(175)</sup>.

Moreover, parallel trade needs to be distinguished from re-importation. In the case of pharmaceuticals, for example, this means transactions where medicinal products are imported into a Member State in which they are authorised, having been previously obtained by a pharmacy in another Member State from a wholesaler in the importing Member State. In this respect the Court held that a product manufactured in a Member State which is exported and then re-imported into this

<sup>(166)</sup> Case C-201/94 *Smith & Nephew* [1996] ECLI:EU:C:1996:432.

<sup>(167)</sup> Case C-100/96 *British Agrochemicals* [1999] ECLI:EU:C:1999:129; Case C-201/06 *Commission v France* [2008] ECLI:EU:C:2008:104, para. 33.

<sup>(168)</sup> Case C-44/01 *Pippig Augenoptik v Hartlauer* [2003] ECLI:EU:C:2003:205, para. 63.

<sup>(169)</sup> Case 104/75 *De Peijper* [1976] ECLI:EU:C:1976:67.

<sup>(170)</sup> Case C-94/98 *Rhône-Poulenc Rorer and May & Baker* [1999] ECLI:EU:C:1999:614, para. 40.

<sup>(171)</sup> Case C-172/00 *Ferring* [2002] ECLI:EU:C:2002:474.

<sup>(172)</sup> Case C-201/94 *Smith & Nephew* [1996] ECLI:EU:C:1996:432, Case C-94/98 *Rhône Poulenc* [1999] ECLI:EU:C:1999:614.

<sup>(173)</sup> Case C-112/02, *Kolpharma* [2004] ECLI:EU:C:2004:208, paras. 15 -18.

<sup>(174)</sup> Case 104/75 *De Peijper* [1976] ECLI:EU:C:1976:67, Case C-201/94 *Smith & Nephew* [1996] ECLI:EU:C:1996:432, Case C-387/18 *Delfarma* [2019] ECLI:EU:C:2019:556.

<sup>(175)</sup> Case C-114/15 *Audace* [2016] ECLI:EU:C:2016:813.

Member State constitutes an imported product in the same way as a product manufactured in another Member State <sup>(176)</sup>. However, the Court pointed out that these findings do not apply if it is established that the products concerned were exported for the sole purpose of re-importation in order to circumvent legislation such as that under consideration <sup>(177)</sup>.

#### 4.1.2. Obligation to use the national language

Language requirements imposed in non-harmonised areas may also constitute a barrier to intra-EU trade in case they result into an additional burden on products originating in other Member States. Hence, they may be prohibited under Article 34 TFEU when products coming from other Member States have to be given a different labelling, which results in additional packaging costs <sup>(178)</sup>. In some instances, it may however be necessary to use national language in order to ensure that the consumers easily understand the information concerning the product in question <sup>(179)</sup>.

In its judgment in *Yannick Geffroy* <sup>(180)</sup>, the Court ruled that Article 34 TFEU ‘must be interpreted as precluding a national rule [...] from requiring the use of a specific language for the labelling of foodstuffs, without allowing for the possibility of using another language easily understood by purchasers or of ensuring that the purchaser is informed by other means’.

When it comes to determining the language easily understood by consumers, the Court stated in *Piageme* <sup>(181)</sup> that various factors may be taken into account such as ‘the possible similarity of words in different languages, the widespread knowledge amongst the population concerned of more than one language, or the existence of special circumstances such as a wide-ranging advertising campaign or widespread distribution of the product, provided that it can be established that the consumer is given sufficient information’.

It follows from the general principle of proportionality that the Member States may adopt national measures requiring that certain information with regard to domestic or imported products must be given in a language that is easily understood by the consumer. However, the national measure at issue must not exclude the possibility to use other means of informing the consumers, such as designs, symbols and pictograms <sup>(182)</sup>. Finally, a measure must be restricted to the information made mandatory by the Member State concerned and for which the use of means other than translation would not be suitable for providing consumers with the appropriate information.

#### 4.1.3. Restrictions on the importation of goods for personal use

Article 34 TFEU not only gives companies the right to import goods for commercial purposes but also entitles individuals to import goods for personal use as shown in *Schumacher* <sup>(183)</sup>. Restrictions with regard to importation of goods for personal use mostly relate to products which are linked with potential risks to human health, such as alcohol, tobacco and

<sup>(176)</sup> Case C-322/01 *DocMorris* [2003] ECLI:EU:C:2003:664, para. 127. See to this effect Case 229/83 *Leclerc and others* [1985] ECLI:EU:C:1985:1, para. 26 and Case C-240/95 *Schmit* [1996] ECLI:EU:C:1996:259, para. 10.

<sup>(177)</sup> Case C-322/01 *DocMorris* [2003] ECLI:EU:C:2003:664, para. 129.

<sup>(178)</sup> Case C-33/97 *Colim v Bigg's Continent Noord* [1999] ECLI:EU:C:1999:274.

<sup>(179)</sup> In this regard, see also:

- Directive 2011/83/EU of the European Parliament and of the Council of 25 October 2011 on consumer rights, amending Council Directive 93/13/EEC and Directive 1999/44/EC of the European Parliament and of the Council and repealing Council Directive 85/577/EEC and Directive 97/7/EC of the European Parliament and of the Council (OJ L 304, 22.11.2011, p. 64),
- Council Directive 93/13/EEC of 5 April 1993 on unfair terms in consumer contracts (OJ L 95, 21.4.1993, p. 29),
- Directive 1999/44/EC of the European Parliament and of the Council of 25 May 1999 on certain aspects of the sale of consumer goods and associated guarantees (OJ L 171, 7.7.1999, p. 12), as well as
- 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 608/2004 (OJ L 304, 22.11.2011, p. 18).

<sup>(180)</sup> Case C-366/98 *Yannick Geffroy* [2000] ECLI:EU:C:2000:430, para. 28.

<sup>(181)</sup> Case C-85/94 *Piageme v Peeters* [1995] ECLI:EU:C:1995:312.

<sup>(182)</sup> Case C-33/97 *Colim v Bigg's Continent Noord* [1999] ECLI:EU:C:1999:274, paras. 41-43.

<sup>(183)</sup> Case 215/87 *Schumacher* [1989] ECLI:EU:C:1989:111.



medicines. In *Schumacher*, a private individual ordered for his own personal use a medicinal preparation from France. However, the customs authorities in Germany, where the individual was residing, refused to grant clearance of the product in question.

The national court asked whether legislation which prohibited a private individual from importing a medicinal preparation for their own personal use that was authorised in the Member State of importation, was available there without prescription, and had been purchased at a pharmacy in another Member State, was contrary to Articles 34 and 36 TFEU. The Court held that such a legislation constituted a breach of Article 34 TFEU, which could not be justified on grounds of the protection of public health. It explained that the purchase of medicinal preparations at a pharmacy in another Member State provided a guarantee of safety equivalent to that of a domestic pharmacy.

However, as shown in *Escalier Bonnarel* <sup>(184)</sup>, private individuals who import goods for use on their own property may also be subject to certain obligations applicable to importers for commercial purposes. In this case, criminal proceedings were brought against two individuals who were accused of having in their possession, and intending to use, pesticide products designed for agricultural use and not having a marketing authorisation. The accused submitted that the national authorisation requirements could not be applied to farmers who were importing products for their own purposes. The Court held that Member States are obliged to submit imports of plant protection products into their territory to a procedure of examination, which can take the form of a 'simplified' procedure, the purpose of which is to verify whether a product requires a marketing authorisation or whether it should be treated as already having been authorised in the Member State of importation <sup>(185)</sup>. The Court pointed out that the above principles apply irrespective of the purpose of importation.

## 5. AGRICULTURAL PRODUCTS

It is worth noting that agricultural products are at the heart of Court rulings on the internal market. This point addresses some specific issues related to these products. Our starting point may be found in Article 38(2) TFEU which states that, save as otherwise provided in Articles 39 to 44 TFEU, the rules laid down for the establishment of the internal market shall apply to agricultural products (these products are defined in the first paragraph of this provision and are listed in Annex I TFEU).

One question which has been the subject of recent judgments of the Court concerns the extent to which Member States may legislate in areas covered by a common organisation of the market. The Court has held that under the common agricultural policy, a competence shared between the European Union and the Member States in accordance with Article 4(2)(d) TFEU, the Member States have legislative powers which allow them to exercise their competence to the extent that the European Union has not exercised its competence <sup>(186)</sup>.

Furthermore, according to settled case-law, where there is a regulation on the common organisation of the markets in a given sector, the Member States are under an obligation to refrain from taking any measures which might undermine or create exceptions to it. Rules which interfere with the proper functioning of a common organisation of the market are also incompatible with such a common organisation, even if the matter in question has not been exhaustively regulated by it <sup>(187)</sup>.

As regards the setting of a minimum price per unit of alcohol for the retail selling of wines, in the absence of a pricing mechanism, the free formation of selling prices on the basis of fair competition is a component of the Regulation (EU) No 1308/2013 of the European Parliament and of the Council establishing a common organisation of the markets in agricultural goods <sup>(188)</sup> and constitutes the expression of the principle of free movement of goods in conditions of effective competition <sup>(189)</sup>.

<sup>(184)</sup> Cases C-260/06 and C-261/06 *Escalier Bonnarel* [2007] ECLI:EU:C:2007:659.

<sup>(185)</sup> *Ibid.*, para. 32.

<sup>(186)</sup> Case C-373/11 *Panellinos Sindesmos Viomikhanion Metapoisis Kapnou* [2013] ECLI:EU:C:2013:567, para. 26.

<sup>(187)</sup> Case C-283/03 *Kuipers* [2005] ECLI:EU:C:2005:314, para. 37 and the case-law cited.

<sup>(188)</sup> Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural goods and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 (OJ L 347, 20.12.2013, p. 671).

<sup>(189)</sup> Case C-333/14 *Scotch Whisky Association and Others* [2015] ECLI:EU:C:2015:845, para. 20.

Nevertheless, the establishment of a common market organisation does not prevent the Member States from applying national rules intended to attain an objective relating to the general interest other than those covered by that common market organisation, even if those rules are likely to have an effect on the functioning of the common market in the sector concerned <sup>(190)</sup>.

In its judgment in the *Scotch Whiskey* case, the Court came to the conclusion that Regulation (EU) No 1308/2013 establishing a common organisation of the markets in agricultural products must be interpreted as not precluding a national measure which imposes a minimum price per unit of alcohol for the retail selling of wines, provided that that measure is in fact an appropriate means of securing the objective of the protection of human life and health and that, taking into consideration the objectives of the common agricultural policy and the proper functioning of the common organisation of agricultural markets, it does not go beyond what is necessary to attain that objective of the protection of human life and health.

In Case C-2/18, the Court took the view that by adopting Regulation (EU) No 1308/2013, in particular, Article 148 thereof, the European Union has not exhaustively exercised its competence in the area of contractual relations between the parties to a contract for the delivery of raw milk. Therefore, that regulation cannot be interpreted as prohibiting Member States, in principle, from adopting measures in that area <sup>(191)</sup>.

The Court also considered that it cannot be established from references to certain unfair practices that the objective of combating unfair practices pursued by the legislation at issue is covered by Regulation (EU) No 1308/2013, especially since such practices are not referred to as a whole, nor regulated by or even identified in that regulation <sup>(192)</sup>. The Court held that this review of proportionality must be carried out by taking into consideration, in particular, the objectives of the common agricultural policy and the proper functioning of the common market organisation, which necessitates that those objectives be weighed against the objective pursued by the national legislation, which is to combat unfair commercial practices <sup>(193)</sup>.

In this case, the Court concluded that the rules at issue do not go beyond what is necessary to achieve the objectives which they pursue. However, it is for the referring court, which is the only court with direct knowledge of the dispute before it, to determine whether the measures adopted to combat unfair commercial practices by strengthening the bargaining power of milk producers who do not belong to a recognised milk producer organisation and, therefore, to contribute to the viable development of production and guarantee a level playing field for milk producers by limiting the principle of freedom to negotiate the price, do not go beyond what is necessary <sup>(194)</sup>.

## 6. EXPORT RESTRICTIONS (ARTICLE 35 TFEU)

Article 35 TFEU states 'Quantitative restrictions on exports, and all measures having equivalent effect, shall be prohibited between Member States'.

### 6.1. Definition of 'Exports'

In the context of Article 35 TFEU, the term 'exports' refers to trade between Member States, i.e. exports from one Member State to another. It does not apply to exports to a country outside of the EU.

### 6.2. Quantitative restrictions and measures having equivalent effect

Although Articles 34 and 35 TFEU have very similar wording, the Court of Justice has treated these two provisions distinctly. Essentially, Article 35 TFEU only applies to measures which discriminate against goods. This principle was established in the *Groenveld* case <sup>(195)</sup>, in which the Court stated that Article 35 TFEU 'concerns national measures which

<sup>(190)</sup> Ibid., para. 26 and the case-law cited.

<sup>(191)</sup> Case C-2/18, *Lietuvos Respublikos Seimo narių grupė* [2019] ECLI:EU:C:2019:962, para. 45.

<sup>(192)</sup> Ibid., para. 49.

<sup>(193)</sup> Ibid., para. 57.

<sup>(194)</sup> Ibid., para. 69.

<sup>(195)</sup> Case 15/79 P. B. *Groenveld BV v Produktschap voor Vee en Vlees* [1979] ECLI:EU:C:1979:253.

have as their specific object or effect the restriction of patterns of exports and thereby the establishment of a difference in treatment between the domestic trade of a Member State and its export trade'. If this provides a 'particular advantage for national production or for the domestic market of the State in question at the expense of the production or of the trade of other Member States' then Article 35 TFEU operates <sup>(196)</sup>.

There are several reasons for the Court's narrow interpretation of Article 35 TFEU as compared to its jurisprudence on Article 34 TFEU. In the case of imports, non-discriminatory measures may place a dual burden on importers if they must comply with the rules in their own country and in the country of importation. Thus, such measures are perceived as being justly caught by EU law protecting the internal market. In contrast, this is not the case for exporters, who merely follow the rules laid down for the domestic market. Secondly, if the scope of Article 35 TFEU were too wide, it could encompass restrictions which have no bearing on intra-EU trade.

In the *Rioja* case, the difference in treatment resulted from better manufacturing or trading conditions for domestic companies <sup>(197)</sup>. In *Parma*, this was brought about by procuring a special advantage for undertakings situated in the region of production. The use of the protected designation 'Prosciutto di Parma' for ham marketed in slices was subject to the condition that slicing and packaging operations be carried out in the region of production <sup>(198)</sup>. Such benefits for the domestic market lead to competitive disadvantages for businesses established in other Member States due to either additional costs that may occur or the difficulty of procuring certain products necessary to enter into competition with the domestic market.

In some of its more recent Article 35 TFEU decisions, the Court introduced an alternative approach to the last requirement of the *Groenvelde* test ('at the expense of the production or of the trade of other Member States') <sup>(199)</sup>. In *Gysbrechts* <sup>(200)</sup>, the Court dealt with Belgian legislation prohibiting the seller from requesting any payment in advance or in the 7 day 'withdrawal' period during which a consumer can withdraw from a distance contract. In this judgment, the Court confirmed the definition established in *Groenvelde*. Nonetheless, it reasoned that although the prohibition on receiving advance payments is applicable to all traders active in the national territory, its actual effect is generally greater on cross-border sales made directly to consumers, and thus on goods leaving the market of the exporting Member State than on the marketing of goods in the domestic market of that Member State. Interestingly, in this case the effects of the barrier primarily hampered the trading activities of companies established in the Member State of export and not in the Member State of destination <sup>(201)</sup>.

The approach in *Gysbrechts* was endorsed in *New Valmar*, a case in which undertakings with a place of establishment within the territory of a Member State were required to draw up all invoices relating to cross-border transactions exclusively in the official language of that State. If this was not done, the invoices concerned would be declared null and void by the national

<sup>(196)</sup> Case 15/79 *P. B. Groenvelde BV v Produktschap voor Vee en Vlees* [1979] ECLI:EU:C:1979:253, para. 7. See also Case C-12/02 *Marco Grilli* [2003] ECLI:EU:C:2003:538, para. 41.

<sup>(197)</sup> Cases C-47/90 *Delhaize v Promalvin* [1992] ECLI:EU:C:1992:250 (in this case, the Court omitted the requirement of providing a particular advantage for national production in its reasoning, even if it was manifestly present in the facts). However, in the subsequent judgment of the Court in Case C-388/95 *Kingdom of Belgium v Kingdom of Spain* [2000] ECLI:EU:C:2000:244, the Court held that the requirement at issue (in effect a bottling-in-the-region requirement for wine with a protected designation of origin) must be regarded as compatible with Community law despite its restrictive effects on trade if it is shown that it is necessary and proportionate and capable of upholding the considerable reputation incontestably enjoyed by the Rioja 'denominación de origen calificada'. The Court held that this was indeed the case essentially because operators in the region have the essential know-how to be able to carry out complex bottling operations. The same reasoning applied to controls carried out in the region. Moreover, bulk transport of wine outside the region entailed risks of deterioration in quality due to oxidation.

<sup>(198)</sup> Case C-108/01 *Consorzio del Prosciutto di Parma* [2003] ECLI:EU:C:2003:296. However, the Court held in that case that a condition such as at issue in the main proceedings (slicing and packaging must be carried out in the region) must be regarded as compatible with EU law, despite its restrictive effects on trade, if it is shown that it is necessary and proportionate and capable of safeguarding the quality of the product at issue, guaranteeing its origin or ensuring the control of the specification of that PGI (see para. 66 of the judgment). The Court took the view that is in particular the case when the procedure laid down in the specification attributes the performance of systematic and thorough controls to experts who have specialist knowledge of the features of the products at issue and it is, therefore, hardly conceivable that such checks could be effectively introduced in other Member States (see para. 75). See also in that sense Case C-469/00 *Ravil v Bellon* [2003] ECLI:EU:C:2003:295. This approach has been confirmed in Case C-367/17 *EA and Others* [2018] ECLI:EU:C:2018:1025 as well as in Case C-569/18 *Caseificio Cirigliana* [2019] ECLI:EU:C:2019:873 (see para. 39).

<sup>(199)</sup> Case 155/80 *Oebel* [1981] ECLI:EU:C:1981:177; Case C-388/95 *Kingdom of Belgium v Kingdom of Spain* [2000] ECLI:EU:C:2000:244, para. 41.

<sup>(200)</sup> Case C-205/07 *Gysbrechts and Santurel Inter* [2008] ECLI:EU:C:2008:730.

<sup>(201)</sup> *Ibid.*, paras 40-43; C-169/17 *Asociación Nacional de Productores de Ganado Porcino* [2018] ECLI:EU:C:2018:440, para 29.

courts of their own motion. Here, the primary criterion for the Court appeared to be whether the actual effect of a measure was greater on goods leaving the market of the exporting Member State <sup>(202)</sup>. It held that such a restriction indeed fell within the scope of Article 35 TFEU. Although the measure's objective of promoting and encouraging the use of one of the official languages of a Member States is a legitimate objective, the measure was nonetheless not considered proportionate <sup>(203)</sup>.

The Court followed the same approach in the *Hidroeléctrica* judgement, where national measures prioritising the supply of electricity on the national market were considered as measures having equivalent effect to a quantitative restriction within the meaning of Article 35 TFEU, because of a greater effect on electricity exports <sup>(204)</sup>.

In the recent *VIPA* judgment, which concerned Hungarian legislation precluding the dispensing of prescription-only medicinal products in Hungary on the basis of orders by healthcare professionals in other Member States, the Court went as far as to say that minor restrictive effects, provided they are neither too indirect nor too uncertain, suffice to show the existence of a measure having equivalent effect within the meaning of Article 35 TFEU <sup>(205)</sup>.

## 7. JUSTIFICATIONS FOR RESTRICTIONS TO TRADE

According to settled case-law of the Court of Justice, national legislation which constitutes a measure having equivalent effect to quantitative restrictions can be justified on one of the grounds of public interest laid down in Article 36 TFEU (see Section 7.1) or by mandatory requirements (see Section 7.2).

In either case, the provision of national law must be appropriate for securing the attainment of the objective pursued and must not go beyond what is necessary in order to attain it (see Section 7.3).

### 7.1. Article 36 TFEU

Article 36 TFEU lists the defences that could be used by Member States to justify national measures that impede cross-border trade: 'The provisions of Articles 34 and 35 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property.'

Additionally, the case-law of the Court provides for so-called 'mandatory requirements' (e.g. environmental protection) which a Member State may also rely on to defend national measures.

The Court of Justice interprets this list of derogations in Article 36 TFEU narrowly, all of which relate to non-economic interests <sup>(206)</sup>. Moreover, any measure must respect the principle of proportionality. The burden of proof in justifying the measures adopted according to Article 36 TFEU lies with the Member State <sup>(207)</sup>. However, when a Member State provides convincing justifications, it is then for the Commission to show that the measures taken are not appropriate in that particular case <sup>(208)</sup>.

Article 36 TFEU cannot be relied on to justify deviations from harmonised EU legislation <sup>(209)</sup>. However, where there is no EU harmonisation, it is up to Member States to define their own levels of protection. In the case of partial harmonisation, the harmonising legislation itself quite often explicitly authorises Member States to maintain or adopt stricter measures provided they are compatible with the Treaty. In such cases, the Court will have to evaluate the provisions in question under Article 36 TFEU.

<sup>(202)</sup> Case C-15/15 *New Valmar* [2016] ECLI:EU:C:2016:464, para. 36. See also Case C-169/17 *Asociación Nacional de Productores de Ganado Porcino* [2018] ECLI:EU:C:2018:440, para. 29.

<sup>(203)</sup> Case C-15/15 *New Valmar* [2016] ECLI:EU:C:2016:464, paras. 47, 50-56.

<sup>(204)</sup> Case C- 648/18 *Hidroeléctrica* [2020] ECLI:EU:C:2020:723 para. 33.

<sup>(205)</sup> Case C-222/18 *VIPA* [2019] ECLI:EU:C:2019:751, para. 62.

<sup>(206)</sup> Case C-120/95 *Decker* [1998] ECLI:EU:C:1998:167; Case 72/83 *Campus Oil* [1984] ECLI:EU:C:1984:256.

<sup>(207)</sup> Case 251/78 *Denkavit Futtermittel v Minister of Agriculture* [1979] ECLI:EU:C:1979:252.

<sup>(208)</sup> Case C-55/99 *Commission v France* [2000] ECLI:EU:C:2000:693.

<sup>(209)</sup> Case C-473/98 *Kemikalieinspektionen v Toolex Alpha* [2000] ECLI:EU:C:2000:379; Case 5/77 *Tadeschi v Denkavit* [1977] ECLI:EU:C:1977:144.

Even if a measure is justifiable under Article 36 TFEU, it must not 'constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States'. The second part of Article 36 TFEU is designed to avoid abuse on the part of Member States. As the Court has stated, 'the function of the second sentence of Article [36] is to prevent restrictions on trade based on the grounds mentioned in the first sentence from being diverted from their proper purpose and used in such a way as to create discrimination in respect of goods originating in other Member States or indirectly to protect certain national products' <sup>(210)</sup>, i.e. to adopt protectionist measures.

Originally, it was considered that distinctly applicable measures may only be justified on grounds of Article 36 TFEU, whereas indistinctly applicable measures could also be justified on grounds of any of the mandatory requirements. However, the classification between distinctly and indistinctly applicable measures is not as relevant as before.

#### 7.1.1. Public morality, policy and security

Member States may decide to ban a product on **morality** grounds. While it is up to each Member State to set the standards enabling goods to comply with national provisions concerning morality, discretion must be exercised in conformity with the obligations arising under EU law. For example, any prohibition on imports of products the marketing of which is restricted but not prohibited will be discriminatory and in breach of the 'free movement of goods' provisions. Most of the cases where the Court has admitted the public morality justification have concerned obscene, indecent articles <sup>(211)</sup>. In other cases where public morality was invoked, other interlinked justifications were found, such as public interest in gambling cases <sup>(212)</sup> or the protection of minors in the case of marking of videos and DVDs <sup>(213)</sup>.

**Public policy** is interpreted very strictly by the Court of Justice and has rarely succeeded as a ground for a derogation under Article 36 TFEU. For example, it will not succeed if it is intended as a general safeguard clause or only to serve protectionist economic ends. Where an alternative Article 36 TFEU derogation would apply, the Court of Justice tends to use the alternative or combine a public policy justification with other possible justifications <sup>(214)</sup>. The public policy justification alone was accepted in one exceptional case, where a Member State restricted the import and export of gold-collectors' coins. The Court held that it was justified on grounds of public policy because it stemmed from the need to protect the right to mint coinage, which is traditionally regarded as involving the fundamental interests of the state <sup>(215)</sup>.

The **public security** justification has been advanced in a specific area, namely the EU energy market, though a decision should be limited to the precise facts of individual cases and is not of wide applicability. In *Campus Oil*, a Member State ordered petrol importers to purchase up to 35 % of their petrol requirements from a national petrol company at prices fixed by the government. The Court of Justice held that the measure was clearly protectionist and constituted a breach of Article 34 TFEU. However, it was held to be justified on the grounds of public security, i.e. for maintaining a viable oil refinery to meet supply in times of crisis <sup>(216)</sup>. The Court also accepted the securing of energy supply as a ground of public security within the meaning of Article 36 TFEU in *Hidroeléctrica* <sup>(217)</sup>.

<sup>(210)</sup> Case 34/79 *Henn and Darby* [1979] ECLI:EU:C:1979:295, para. 21, as well as Joined Cases C-1/90 and C-176/90 *Aragonesa de Publicidad Exterior and Publivia* [1991] ECLI:EU:C:1991:327, para. 20.

<sup>(211)</sup> Case 121/85 *Conegate v Customs and Excise Commissioners* [1986] ECLI:EU:C:1986:114 ; Case 34/79 *R v Henn and Darby* [1979] ECLI:EU:C:1979:295 .

<sup>(212)</sup> Case C-275/92 *Schindler* [1994] ECLI:EU:C:1994:119, para. 58; Case C-124/97 *Läärä and Others* [1999] ECLI:EU:C:1999:435, para. 33; Case C-98/14 *Berlington Hungary* [2015] ECLI:EU:C:2015:386, para. 58.

<sup>(213)</sup> Case C-244/06 *Dynamic Medien Vertriebs v Avides Media* [2008] ECLI:EU:C:2008:85.

<sup>(214)</sup> It has been admitted by the Court that legislation 'which has as its objective the control of the consumption of alcohol so as to prevent the harmful effects caused to health and society by alcoholic substances, and thus seeks to combat alcohol abuse, reflects health and public policy concerns recognised by Article [36 TFEU]' – Case C-434/04 *Ahokainen and Leppik* [2006] ECLI:EU:C:2006:609, para. 28; See also Case C-170/04 *Rosengren and Others* [2007] ECLI:EU:C:2007:313, para. 40; Case C-198/14 *Visnapuu* [2015] ECLI:EU:C:2015:751, para. 116.

<sup>(215)</sup> Case 7/78 *R v Thompson* [1978] ECLI:EU:C:1978:209.

<sup>(216)</sup> Case 72/83 *Campus Oil* [1984] ECLI:EU:C:1984:256.

<sup>(217)</sup> Case C-648/18 *Hidroeléctrica* [2020] ECLI:EU:C:2020:723 para 36

The Court has also accepted the justification on the grounds of public security in cases involving trade of strategically sensitive goods <sup>(218)</sup>, as ‘...the risk of serious disturbance in foreign relations or to peaceful coexistence of nations may affect the security of a Member State’. In these cases, the Court stated that the scope of Article 36 TFEU covers both internal security (e.g. crime detection and prevention and regulation of traffic) and external security <sup>(219)</sup>.

#### 7.1.2. Protection of the health and life of humans, animals and plants (precautionary principle)

The Court of Justice has ruled that ‘the health and life of humans rank first among the property or interests protected by Article [36] and it is for Member States, within the limits imposed by the Treaty, to decide what degree of protection they intend to assure, and in particular how strict the checks to be carried out are to be’ <sup>(220)</sup>. In the same ruling, the Court stated that national rules or practices do not fall within the exception specified in Article 36 TFEU if the health and life of humans can be as effectively protected by measures which are less restrictive to intra-EU trade. <sup>(221)</sup>

The protection of health and life of humans, animals and plants is the most popular justification which Member States use to justify obstacles to the free movement of goods. While Member States are allowed a certain degree of discretion <sup>(222)</sup>, some principal rules must be observed. It must be shown that the marketing of products poses a serious and real risk to public health <sup>(223)</sup>. This must be well founded, and Member States must provide all evidence, data (technical, scientific, statistical, nutritional, etc) and other relevant information <sup>(224)</sup>. The protection of health cannot be invoked if the real purpose of the measure is to protect the domestic market, even if in the absence of harmonisation it is for a Member State to decide on the level of protection. Measures adopted must also be proportionate, i.e. restricted to what is necessary to attain the legitimate aim of protecting public health <sup>(225)</sup>.

**Application of the ‘precautionary principle’:** Though perhaps implicitly included in earlier case law, the precautionary principle was first explicitly acknowledged by the Court of Justice in the *National Farmers Union* case <sup>(226)</sup>. The Court stated, ‘where there is uncertainty as to the existence or extent of risks to human health, the institution may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent’. The principle defines the circumstances in which a legislator, whether national, EU or international, can adopt measures to protect consumers against health risks which, given uncertainties of the present state of scientific research, are possibly associated with a product or service.

Generally, when Member States wish to maintain or introduce measures to protect health under Article 36 TFEU, the burden of proving the necessity of such measures rests with them <sup>(227)</sup>. This is also the case in situations where the precautionary principle is concerned <sup>(228)</sup>. In its rulings, the Court has emphasised that real risks need to be demonstrated in the light of the most recent results of international scientific research. The Court of Justice has consistently stated that the Member States have to perform a detailed risk assessment before taking precautionary measures under Articles 34

<sup>(218)</sup> Case C-367/89 *Criminal proceedings against Aimé Richardt and Les Accessoires Scientifiques SNC* [1991] ECLI:EU:C:1991:376.

<sup>(219)</sup> *Ibid.*

<sup>(220)</sup> Case 104/75 *De Peijper* [1976] ECLI:EU:C:1976:67.

<sup>(221)</sup> See also Case C-333/14 *Scottish Whiskey Association* [2015] ECLI:EU:C:2015:845, para. 59.

<sup>(222)</sup> Case C-198/14 *Visnapuu* [2015] ECLI:EU:C:2015:751, para. 118 ; Case C-108/09 *Ker-Optika* [2010] ECLI:EU:C:2010:725, para. 58.

<sup>(223)</sup> Case C-270/02 *Commission v Italy* [2004] ECLI:EU:C:2004:78, para. 22 ; Case C-319/05 *Commission v Germany* [2007] ECLI:EU:C:2007:678, para. 88; C-421/09 *Humanplasma GmbH v Austria* [2010] ECLI:EU:C:2010:760, para. 34.

<sup>(224)</sup> Case C-270/02 *Commission v Italy* [2004] ECLI:EU:C:2004:78; Case C-319/05 *Commission v Germany* [2007] ECLI:EU:C:2007:678; Case C-148/15 *Deutsche Parkinson Vereinigung* [2016] ECLI:EU:C:2016:776, paras. 36, 40;

<sup>(225)</sup> Case C-108/09 *Ker-Optika* [2010] ECLI:EU:C:2010:725, para. 35.

<sup>(226)</sup> Case C-157/96 *National Farmers Union* [1998] ECLI:EU:C:1998:191, para. 63.

<sup>(227)</sup> See for example Case 227/82 *Van Bennekom* [1983] ECLI:EU:C:1983:354, para. 40 and Case 178/84 *Commission v Germany (Reinheitsgebot)* [1987] ECLI:EU:C:1987:126, para. 46.

<sup>(228)</sup> Case C-41/02 *Commission v Netherlands* [2004] ECLI:EU:C:2004:762, para. 47; Case C-192/01 *Commission v Denmark* [2003] ECLI:EU:C:2003:492, para. 46; Case C-24/00 *Commission v France* [2004] ECLI:EU:C:2004:70, para. 53.

and 36 TFEU <sup>(229)</sup>. However, Member States do not need to show a definite link between the evidence and the risk <sup>(230)</sup>. If scientific uncertainty as to risk persists and has been established, the Court leaves the Member States or the relevant institutions considerable leeway in deciding on what protective measures to take <sup>(231)</sup>. In Case C-446/08 *Solgar Vitamin's*, concerning the setting of maximum amounts of vitamins or minerals used in the manufacture of food supplements, the Court confirmed that Member States do not need to wait until the seriousness and reality of those risks are demonstrated fully <sup>(232)</sup>. However, the measures cannot be based on 'purely hypothetical considerations' <sup>(233)</sup>, as confirmed in Case C-672/15 *Noria Distribution*, which also considered upper safe limits of vitamins and minerals in the manufacture of food supplements <sup>(234)</sup>.

#### 7.1.3. Protection of national treasures possessing artistic, historic or archaeological value

A Member State's duty to protect its national treasures and patrimony may justify measures which create obstacles to imports or exports.

Member States impose different restrictions on the export of antiques and other cultural artefacts and these could be considered to be justified under Article 36 TFEU.

In *LIBRO*, the Court of Justice considered that the protection of cultural diversity 'in general cannot be considered to come within the protection of national treasures possessing artistic, historic or archaeological value within the meaning of Article 36 TFEU' <sup>(235)</sup>.

#### 7.1.4. Protection of industrial and commercial property

Article 36 TFEU refers to the 'protection of industrial and commercial property' as a justification ground for the restriction on imports, exports or goods in transit. 'Industrial and commercial property' generally refers to intellectual property (IP) rights such as patents, trade marks, designs, copyright and geographical indications <sup>(236)</sup>.

In its original case-law, the Court of Justice EU developed a number of principles which have been important for defining the scope of the derogation at national level, but also to pave the way towards the harmonisation and unification of IP rights at EU level (which discussion goes beyond the scope of this chapter).

The first principle is that the Treaty does not affect the *existence* of IP rights granted pursuant to the legislation of the Member States. Accordingly, national legislation on the acquisition, transfer and extinction of such rights is lawful. This principle does not apply, however, where there is an element of discrimination in the national rules <sup>(237)</sup>.

The second principle is the *exhaustion of rights* doctrine. The IP holder may restrict the use, manufacture and sale of the IP protected product within the Member State where this right is granted. However, once the IP owner has him/herself or with his/her consent lawfully sold and distributed the product in the Member State, the IP right is *exhausted* at the border. The owner of the right may then no longer oppose the importation of the product into any Member State where it was first marketed, allowing for parallel imports from anywhere in the EU.

<sup>(229)</sup> Case C-249/07 *Commission v Netherlands* [2008] ECLI:EU:C:2008:683, para. 50-51; Case C-41/02 *Commission v Netherlands* [2004] ECLI:EU:C:2004:762; Case C-192/01 *Commission v Denmark* [2003] ECLI:EU:C:2003:492; Case C-24/00 *Commission v France* [2004] ECLI:EU:C:2004:70.

<sup>(230)</sup> The Commission has adopted a communication on the precautionary principle (COM (2000) 1 final).

<sup>(231)</sup> Cf. Case C-132/03 *Codacons and Federconsumatori* [2005] ECLI:EU:C:2005:310, para. 61 and Case C-236/01 *Monsanto Agricoltura* [2003] ECLI:EU:C:2003:431, para. 111.

<sup>(232)</sup> Case C-446/08 *Solgar Vitamin's France* [2010] ECLI:EU:C:2010:233, para. 67.

<sup>(233)</sup> Case C-236/01 *Monsanto Agricoltura* [2003] ECLI:EU:C:2003:431, para. 106; Case C-41/02 *Commission v Netherlands* [2004] ECLI:EU:C:2004:762, para. 52; Case C-192/01 *Commission v Denmark* [2003] ECLI:EU:C:2003:492, para. 49; Case C-24/00 *Commission v France* [2004] ECLI:EU:C:2004:70, para. 56; Case C-446/08 *Solgar Vitamin's France* [2010] ECLI:EU:C:2010:233, para. 67.

<sup>(234)</sup> Case C-672/15 *Noria Distribution SARL* [2017] ECLI:EU:C:2017:310, para. 33.

<sup>(235)</sup> Case C-531/07 *Fachverband der Buch- und Medienwirtschaft v LIBRO* [2009] ECLI:EU:C:2009:276, para. 32.

<sup>(236)</sup> See for a list of specific IPs the Statement of the Commission concerning Article 2 of Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights (2005/295/EC) (OJ L 94, 13.4.2005, p. 37).

<sup>(237)</sup> Case C-235/89 *Commission v Italy* [1992] I-777.

The exhaustion of rights doctrine intends to balance the protection of industrial property rights with the free movement of goods. Derogations are only allowed in so far as they are justified for the purpose of safe-guarding *the specific subject-matter* of that property. That principle makes it possible to determine, in relation to each category of IP, the conditions in which the exercise of the right will be permissible under EU law, even though in a cross-border situation such exercise impedes by definition free movement. The Court's case-law on exhaustion applies in particular to patents, trade marks, designs <sup>(238)</sup> and copyright <sup>(239)</sup>.

For patents, for instance, the Court accepted as the subject-matter in particular 'to reward the creative efforts of the inventor, to guarantee that the patentee has the exclusive right to use an invention with a view to manufacturing industrial products and putting them into circulation for the first time, either directly or by the grant of licences to third parties, as well as the right to oppose infringements' <sup>(240)</sup>. It is then for the holder of the patent to decide under which circumstances he wishes to market his product, including the option of marketing in a Member State where the product does not benefit from patent protection. If the patent holder does so, he must accept the consequences of his choice as regards the free movement of the product within the single market. Permitting an inventor to invoke a patent he holds in one Member State to prevent the importation of that product freely marketed by the inventor in another Member State where that product was not patentable, would cause a partitioning of national markets contrary to the aim of the Treaty <sup>(241)</sup>.

For trade marks, the Court ruled in consistent case law that its specific subject matter is in particular to guarantee to the proprietor of the trade mark that he has the right to use that trade mark for the purpose of putting a product into circulation for the first time. This should protect the trademark proprietor against competitors wishing to take advantage of the status and reputation of the trade mark by selling products illegally bearing that mark. In order to determine the exact scope of this right, the Court considered that regard must be had to the essential function of the trade mark, which is to guarantee the identity of the origin of the marked product to the consumer or ultimate user by enabling him without any possibility of confusion to distinguish that product from products which have another origin <sup>(242)</sup>.

This case-law has been developed and fine-tuned particularly in the area of repackaging of pharmaceutical products <sup>(243)</sup>.

It should be recalled that the Court delivered this case-law in the absence of corresponding secondary EU legislation. As it held, 'in the presence state of Community law and in the absence of Community standardization or harmonization of laws, the determination of the conditions and procedures under which such protection is granted is a matter for national rules' <sup>(244)</sup>. In the meantime, however, the EU legislator adopted an important set of directives and regulations on IP. The legal framework for trademarks, for instance, is harmonised by means of the Trademark Directive (EU) 2015/2436 of the European Parliament and of the Council <sup>(245)</sup> ('Trademark Directive') and unified under Regulation (EU) 2017/1001 of the European Parliament and Council on the European Union trade mark <sup>(246)</sup>. Similar legislation exists for designs, whereas the harmonisation of national patent laws is still rather fragmented <sup>(247)</sup>.

In the area of copyright and related rights, the EU legislator have broadly harmonised the laws of Member States by granting authors and other right holders a high level of protection. This includes, among other things, exclusive rights to authorise or prohibit certain acts of exploitation of their content, with a harmonised term of protection, a framework of exceptions and limitations, legal protection of technological protection measures and rights management information, collective

<sup>(238)</sup> See, for instance, Case 53/87, *Circa and other v Renault*, ECLI:EU:1988:472.

<sup>(239)</sup> See, for instance, Case C-5/11, *Donner*, ECLI:EU:C:2012:370, par. 31-37, with references to previous case-law.

<sup>(240)</sup> See, for instance, Joined Cases C-267/95 and C-268/95, *Merck & Co e.a. v Primecrown Ltd e.a.* ECLI:EU:C:1996:468, par. 30, with references to previous case-law.

<sup>(241)</sup> See Joined Cases C-267/95 and C-268/95, *Merck & Co e.a. v Primecrown Ltd e.a.* ECLI:EU:C:1996:468, par. 32, with references to previous case-law.

<sup>(242)</sup> See Case C-10/89, *SA CNL-SUCAL NV v HAG GF AG*, ECLI:EU:1990:359, par. 14, with references to previous case-law.

<sup>(243)</sup> See for a good overview of the Court's jurisprudence Case C-143/00, *Boehringer Ingelheim*, ECLI:EU:C:2002:246.

<sup>(244)</sup> Case 53/87, *Circa and other v Renault*, ECLI:EU:1988:472, par. 10.

<sup>(245)</sup> Directive (EU) 2015/2436 of the European Parliament and of the Council of 16 December 2015 to approximate the laws of the Member States relating to trademarks (OJ L 336, 23.12.2015, p. 1), Article 15(1).

<sup>(246)</sup> Regulation (EU) 2017/1001 of the European Parliament and Council of 14 June 2017 on the European Union trade mark (OJ L 154, 16.6.2017, p. 1).

<sup>(247)</sup> See for an overview of this IP legislation [https://ec.europa.eu/growth/industry/policy/intellectual-property\\_en](https://ec.europa.eu/growth/industry/policy/intellectual-property_en)



management of rights and enforcement of rights. In the area of the free movement of goods, Directive 2001/29/EC of the European Parliament and Council <sup>(248)</sup> provides authors with the exclusive right of distribution of their works. Directive 2006/115/EC of the European Parliament and Council <sup>(249)</sup> provides performers, phonogram producers, film producers and broadcasting organisations with the exclusive right of distribution of their protected subject matter. Directive 2009/24/EC of the European Parliament and Council <sup>(250)</sup> also provides for an exclusive right for the distribution of computer programs.

The three copyright directives mentioned above also provide that the first sale or other transfer of ownership in the Union of a copy of the work or other protected subject matter by the right holder or with his consent exhaust the distribution right of that copy within the Union. This rule ensures the free movement of copyright-protected goods within the Union once they have been put onto the market by the right holder or with his consent. The Court of Justice has clarified that this principle applies with respect to tangible copies of works and other protected matter. However, in the case of computer programs, the Court has clarified that the right of distribution of a copy of a computer program is also exhausted following the downloading of that copy from the internet with the consent of the right holder, under certain conditions that make that downloading equivalent to a sale of the copy of the computer program <sup>(251)</sup>. The Court has recently ruled that this extension of the rule of exhaustion following the online transmission of digital copies does not apply in the case of works other than computer programs (e.g. e-books) <sup>(252)</sup>.

Furthermore, the Court of Justice has provided specific rules for geographical indications for the purposes of Article 36 TFEU <sup>(253)</sup>.

## 7.2. Mandatory requirements

In its *Cassis de Dijon* judgment, the Court of Justice laid down the concept of mandatory requirements as a non-exhaustive list of protected interests in the framework of Article 34 TFEU. In this judgment, the Court stated that these mandatory requirements relate in particular to the effectiveness of fiscal supervision, the protection of public health, the fairness of commercial transactions and the defence of the consumer <sup>(254)</sup>. The terminology of the Court has subsequently changed – nowadays, the Court often refers to overriding requirements in the public interest or in the general interest instead of mandatory requirements.

Mandatory requirements may be invoked to justify national measures capable of hindering trade within the internal market and not falling within the exceptions laid down in Article 36 TFEU. The justification assessment is the same as under Article 36 – in order to be permissible, national measures must be proportionate to the objective pursued. In principle, mandatory requirements may only justify national measures which are indistinctly applicable to domestic goods and to goods originating from other Member States <sup>(255)</sup>. Therefore, grounds other than those covered by Article 36 TFEU may theoretically not be used to justify discriminatory measures. While the Court has found ways to overcome this separation without renouncing its earlier practice <sup>(256)</sup>, it has been argued that such a separation is artificial and the Court is moving towards simplification by treating mandatory requirements in the same way as Article 36 TFEU justifications.

<sup>(248)</sup> Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the harmonisation of certain aspects of copyright and related rights in the information society (OJ L 167, 22.6.2001, p. 10).

<sup>(249)</sup> Directive 2006/115/EC of the European Parliament and of the Council of 12 December 2006 on rental right and lending right and on certain rights related to copyright in the field of intellectual property (OJ L 376, 27.12.2006, p. 28).

<sup>(250)</sup> Directive 2009/24/EC of the European Parliament and of the Council of 23 April 2009 on the legal protection of computer programs (OJ L 111, 5.5.2009, p. 16).

<sup>(251)</sup> Judgment of the Court of Justice on Case C-128/11 *Usedsoft*.

<sup>(252)</sup> Judgment of the Court of Justice on Case C-263/18 *Tom Kabinet*.

<sup>(253)</sup> Case C-3/91 *Exportur v LOR* [1992] ECR I-5529, para. 37; Case C-216/01 *Budějovický Budvar* [2003] ECLI:EU:C:2003:618, para. 99.

<sup>(254)</sup> Case 120/78 *Rewe v Bundesmonopolverwaltung für Branntwein* [1979] ECLI:EU:C:1979:42, para. 8.

<sup>(255)</sup> See, for instance, Joined Cases C-1/90 and C-176/90 *Aragonesa de Publicidad Exterior and Publivia v Departamento de Sanidad y Seguridad Social de Cataluña* [1991] ECLI:EU:C:1991:327, para.13.

<sup>(256)</sup> See for instance Case C-2/90 *Commission v Belgium* [1992] ECLI:EU:C:1992:310, in which the Court decided that the measure which could be seen as discriminatory was not discriminatory because of the special nature of the subject matter of the case and then allowed the environmental justification. In Case C-320/03 *Commission v Austria* [2005] ECLI:EU:C:2005:684, the Court chose to regard a measure as indistinctly applicable instead of indirectly discriminatory.

### 7.2.1. Protection of the environment

Although protection of the environment is not expressly mentioned in Article 36 TFEU, it has been recognised by the Court as a mandatory requirement. The Court takes the view that ‘...the protection of the environment is one of the [Union’s] essential objectives, which may as such justify certain limitations of the principle of free movement of goods’ <sup>(257)</sup>. In fact, the high level of environmental protection was already recognised as an objective in the general interest in the 1980s and 90s <sup>(258)</sup>.

The Court has recognised a variety of measures and aims to go under the protection of the environment, including:

- National support schemes for green electricity inasmuch as they contribute to the reduction of greenhouse gas emissions, which are amongst the main causes of climate change that the European Union and its Member States have pledged to combat <sup>(259)</sup>;
- Imposing a national sustainability verification system for bio-liquids under which all the economic operators involved in the supply chain are bound by certain requirements <sup>(260)</sup>;
- Protection of ambient air quality;

The protection of ambient air quality was discussed in two cases (C-28/09 and C-320/03) concerning national measures which aimed at reducing the specific emissions of motor vehicles and the density of road traffic for the purposes of decreasing nitrogen dioxide emission in the province of Tyrol. Such measures included sectoral driving bans, which prohibited lorries of over 7,5 tonnes carrying certain goods from using a section of the A12 motorway in Austria. While such measures could, in principle, be justified on grounds of protection of ambient air quality as a part of the protection of the environment and health of humans, they were not proportionate to meet the desired objectives.

- The use of renewable energy sources for the production of biogas;

Case *E.ON Biofor Sverige* concerned a verification system for the sustainability of biogas. The system in place in Sweden had the factual effect that sustainable biogas produced in Germany and intended for transport into Sweden via the German and Danish gas networks could not be included in the verification system relating to the sustainability of the biogas nor be classified as ‘sustainable’ <sup>(261)</sup>.

The Court noted that the use of renewable energy sources for the production of biogas is, in principle, useful for the protection of the environment, as such legislation is intended to ensure to contribute to the reduction of greenhouse gas emissions. It stated further that the increase in the use of renewable energy sources constitutes one of the important components of the package of measures needed to reduce greenhouse gas emissions and to comply with EU and international greenhouse gas emission reduction commitments and that such an increase is also designed to protect the health and life of humans, animals and plants <sup>(262)</sup>.

- A deposit-and-return system for containers <sup>(263)</sup>.

Protection of the environment is invoked by Member States with increasing frequency due to, inter alia, climate change commitments, scientific progress and greater public awareness. However, the Court has confirmed that public health and environmental justifications are not always sufficient to inhibit the free movement of goods. In several cases, the Court has upheld the Commission’s arguments that the national measures were disproportionate to the aim to be achieved or that there was a lack of evidence to prove the claimed risk <sup>(264)</sup>.

<sup>(257)</sup> Case 302/86 *Commission v Denmark* [1988] ECLI:EU:C:1988:421, para. 8.

<sup>(258)</sup> Case 240/83 *Procureur de la République v ADBHU* [1985] ECLI:EU:C:1985:59, paras 12-13, 15; Case 302/86, *Commission v Denmark* [1988] ECLI:EU:C:1988:421, paras. 8-9; Case C-487/06 *British Aggregates v Commission* [2008] ECLI:EU:C:2008:757, para. 91.

<sup>(259)</sup> Case C-573/12 *Ålands Vindkraft* [2014] ECLI:EU:C:2014:2037, para. 78.

<sup>(260)</sup> Case C-242/17 *L.E.G.O.* [2018] ECLI:EU:C:2018:804, para. 72.

<sup>(261)</sup> Case C-549/15 *E.ON Biofor Sverige* [2017] ECLI:EU:C:2017:490, paras. 74, 80 and 84.

<sup>(262)</sup> *Ibid.*, paras. 88-89.

<sup>(263)</sup> Case 302/86 *Commission v Denmark* [1988] ECLI:EU:C:1988:421. However, as mentioned above, deposit schemes are partly covered by Directive 94/62/EC of 20 December 1994 on packaging and packaging waste and Directive (EU) 2018/852 of the European Parliament and of the Council of 30 May 2018 amending Directive 94/62/EC on packaging and packaging waste (OJ L 150, 14.6.2018, p. 141).

<sup>(264)</sup> See for example: Case C-319/05 *Commission v Germany* [2007] ECLI:EU:C:2007:678; Case C-186/05 *Commission v Sweden* [2007] ECLI:EU:C:2007:571; Case C-297/05 *Commission v Netherlands* [2007] ECLI:EU:C:2007:531; Case C-254/05 *Commission v Belgium* [2007] ECLI:EU:C:2007:319; Case C-432/03 *Commission v Portugal* [2005] ECLI:EU:C:2005:669.

Protection of the environment serves as a good example of the more flexible approach adopted by the Court in terms of categorising the justifications. The Court has acknowledged in several instances that the protection of the environment is related to the objectives of protecting human, animal and plant life or health, too <sup>(265)</sup>. The Court stated in *Commission v Austria* that it is apparent from Article 174(1) EC (now 191 TFEU) that the protection of human health is one of the objectives of Union policy on the environment. It stated further that those objectives are closely linked, particularly in connection with the fight against air pollution, the purpose of which is to limit the dangers to health connected with the deterioration of the environment. The objective of protection of health is therefore already incorporated, in principle, in the objective of protection of the environment <sup>(266)</sup>.

### 7.2.2. Consumer protection

Consumer protection is among the most frequently invoked justifications. The information which must be provided for consumers is evaluated on the basis of 'the presumed expectations of an average consumer that is reasonably well-informed and reasonably observant and circumspect' <sup>(267)</sup>. This has been stated in Case C-481/12 *Juvelta*, for instance, which concerned hallmarks of precious metals. The Court noted that a requirement that an importer cause to be affixed on articles of precious metal a hallmark indicating their fineness is, in principle, of a nature such as to ensure effective protection for consumers and to promote fair trading. However, the Court stated that a Member State may not require a fresh hallmark to be affixed to products imported from another Member State in which they have been lawfully marketed and hallmarked, where the information provided by the hallmark is equivalent to that prescribed by the Member State of importation and intelligible to consumers of that State <sup>(268)</sup>.

The underlying principle is that consumers, who are given appropriate information in a clear manner, are able to make choices for themselves. The Court has taken a standing according to which a wider choice with quality differences benefits the consumers more than a narrow choice with higher quality based on national standards <sup>(269)</sup>. In case of a serious risk of misleading the consumer, a product may be prohibited.

However, the guiding line in the case law of the Court is that, where imported products are similar to domestic ones, adequate labelling, which may be required under national legislation, will be sufficient to provide the consumer with the necessary information on the nature of the product. No justification on the grounds of consumer protection is admissible for unnecessarily restrictive measures <sup>(270)</sup>.

### 7.2.3. Other mandatory requirements

Over time, the Court has recognised other mandatory requirements capable of justifying obstacles to the free movement of goods, such as:

- **Fundamental rights:** In *Schmidberger*, the Court acknowledged that in some cases, the protection of fundamental rights (in this case freedom of expression and freedom of assembly) must be reconciled with the fundamental freedoms enshrined in the Treaty, where the former are relied upon as justification for a restriction of the latter <sup>(271)</sup>.
- **Improvement of working conditions:** While health and safety at work fall under the heading of public health in Article 36 TFEU, the improvement of working conditions constitutes a mandatory requirement even in the absence of any health consideration <sup>(272)</sup>.

<sup>(265)</sup> Case C-242/17 *L.E.G.O.* [2018] ECLI:EU:C:2018:804, para. 65; Case C-573/12 *Ålands Vindkraft* [2014] ECLI:EU:C:2014:2037, paras. 79 and 93.

<sup>(266)</sup> Case C-28/09 *Commission v Austria* [2011] ECLI:EU:C:2011:854, paras. 121-122; Case C-67/97 *Bluhme* [1998] ECLI:EU:C:1998:584.

<sup>(267)</sup> Case C-481/12 *Juvelta* [2014] ECLI:EU:C:2014:11, para. 23.

<sup>(268)</sup> Case C-481/12 *Juvelta* [2014] ECLI:EU:C:2014:11, para. 21-22; Case 220/81 *Robertson and Others* [1982] ECLI:EU:C:1982:239, para. 11-12.

<sup>(269)</sup> Case C-456/10 *ANETT* [2012] ECLI:EU:C:2012:241, para. 54.

<sup>(270)</sup> Case C-448/98 *Guimont* [2000] ECLI:EU:C:2000:663 concerning the French legislation reserving the designation Emmenthal to a certain category of cheese with rind, Case 261/81 *Rau v De Schmedt* [1982] ECLI:EU:C:1982:382 concerning the Belgian requirement that margarine be sold in cubes.

<sup>(271)</sup> Case C-112/00 *Schmidberger* [2003] ECLI:EU:C:2003:333, para. 77.

<sup>(272)</sup> In Case 155/80 *Oebel* [1981] ECLI:EU:C:1981:177, the Court of Justice stated that the prohibition on night baking was a legitimate economic and social policy decision in a manifestly sensitive sector.

- **Cultural aims** <sup>(273)</sup>: In a case relating to French legislation aimed at encouraging the creation of cinematographic works, the Court seemed to acknowledge that the protection of culture may under specific conditions constitute a mandatory requirement capable of justifying restrictions on imports or exports. In addition, the protection of books as cultural objects has been recognised as an overriding requirement in the public interest <sup>(274)</sup>.
- **Maintenance of press diversity** <sup>(275)</sup>: Following a preliminary reference concerning the Austrian ban on publications offering readers the chance to take part in games for prizes, the Court held that maintenance of press diversity may constitute an overriding requirement in the public interest. It noted that such diversity helps to safeguard freedom of expression, as protected by Article 10 of the European Convention on Human Rights and Fundamental Freedoms.
- **Financial balance of the social security system**: Purely economic aims cannot justify an obstacle to the free movement of goods. However, in Case C-120/95 *Decker*, the Court acknowledged that the risk of seriously undermining the financial balance of the social security system may constitute an overriding reason in the general interest capable of justifying a barrier to the free movement of goods. <sup>(276)</sup>
- **Road safety**: In several cases, the Court has also acknowledged that road safety constitutes an overriding reason in the public interest capable of justifying a hindrance to the free movement of goods <sup>(277)</sup>.
- **Fight against crime**: In a case concerning a Portuguese ban on the affixing of tinted window film on cars <sup>(278)</sup>, the Court found that the fight against crime may constitute an overriding reason in the public interest capable of justifying a hindrance to the free movement of goods.
- **Protection of animal welfare**: In Case C-219/07, the Court noted that the protection of animal welfare is a legitimate objective in the public interest. It also stated that the importance of this objective is reflected in the adoption by the Member States of the Protocol on the protection and welfare of animals, annexed to the Treaty establishing the European Community <sup>(279)</sup>.
- **Promoting and encouraging the use of one of the official languages of a Member State**: The Court has also held that promoting and encouraging the use of an official language of a Member State may constitute a legitimate objective which, in principle, can justify a restriction on the obligations imposed by EU law <sup>(280)</sup>.

As mentioned above, the list of mandatory requirements is not exhaustive but instead constantly evolving in the case law of the Court.

### 7.3. Proportionality test

In order to be justified on grounds of Article 36 TFEU or the mandatory requirements established in the case law of the Court of Justice, a State measure has to comply with the principle of proportionality <sup>(281)</sup>. The principle of proportionality necessitates that the means chosen by the Member States are confined to what is actually appropriate and necessary to safeguard the legitimate objective pursued <sup>(282)</sup>. Simply put, appropriateness requires that the measure in question is

<sup>(273)</sup> Joined Cases 60/84 and 61/84 *Cinéthèque SA v Fédération nationale des cinémas français* [1985] ECLI:EU:C:1985:329.

<sup>(274)</sup> Case C-531/07 *Fachverband der Buch- und Medienwirtschaft* [2009] ECLI:EU:C:2009:276, para. 34.

<sup>(275)</sup> Case C-368/95 *Familiapress* [1997] ECLI:EU:C:1997:325.

<sup>(276)</sup> Case C-120/95 *Decker* [1998] ECLI:EU:C:1998:167, para. 39-40 and opinion of the Advocate General Szpunar in Case C-148/15 *Deutsche Parkinson Vereinigung* [2016] ECLI:EU:C:2016:394, para. 42.

<sup>(277)</sup> See, for instance, Case C-54/05 *Commission v Finland* [2007] ECLI:EU:C:2007:168, para. 40 and case-law cited and Case C-61/12 *Commission v Lithuania* [2014] ECLI:EU:C:2014:172, para. 59.

<sup>(278)</sup> Case C-265/06 *Commission v Portugal* [2008] ECLI:EU:C:2008:210, para. 38.

<sup>(279)</sup> Case C-219/07 *Nationale Raad van Dierenkwekers en Liefhebbers and Andibel* [2008] ECLI:EU:C:2008:353, para. 27.

<sup>(280)</sup> Case C-15/15 *New Valmar* [2016] ECLI:EU:C:2016:464, para. 50. See, to that effect Case 379/87 *Groener v Minister for Education and City of Dublin Vocational Education Committee* [1989] ECLI:EU:C:1989:599, para.19; Case C-391/09 *Runevič-Vardyn and Wardyn* [2011] ECLI:EU:C:2011:291, para. 85, and Case C-202/11 *Las* [2013] ECLI:EU:C:2013:239, para. 25-27.

<sup>(281)</sup> Case C-390/99 *Canal Satellite Digital* [2002] ECLI:EU:C:2002:34, para. 33; Case C-254/05 *Commission v Belgium* [2007] ECLI:EU:C:2007:319, para. 33 and case-law cited; Case C-286/07 *Commission v Luxembourg* [2008] ECLI:EU:C:2008:251, para. 36.

<sup>(282)</sup> See, for instance, Case C-320/03 *Commission v Austria* [2005] ECLI:EU:C:2005:684, para. 85 and Case C-319/05 *Commission v Germany* (Garlic) [2007] ECLI:EU:C:2007:678, para. 87 and case-law cited.

suitable for attaining the desired objective, whereas necessity requires that the means chosen do not restrict the free movement of goods more than what is necessary. In this context, it must be assessed whether there are any means which have a less restrictive effect on intra-Union trade, but which nevertheless reach the same result. Hence, an important element in the analysis of the justification provided by a Member State is the existence of alternative measures. On several occasions, the Court has found that State measures were not proportionate due to the fact that alternative measures were available <sup>(283)</sup>.

For instance, in Cases C-28/09 and C-320/03, the Court stated that before adopting a measure so radical as a total traffic ban on a section of motorway constituting a vital route of communication between certain Member States, the authorities are under a duty to examine carefully the possibility of using measures less restrictive of freedom of movement, and discount them only if their inappropriateness to the objective pursued was clearly established <sup>(284)</sup>. In Case C-549/15 concerning a verification system for the sustainability of biogas, the Court considered that it was not shown that the exception to the principle of the free movement of goods was necessary in order to attain the objectives concerned. This was due to the fact that the authorities had failed to demonstrate specifically the existence of a reason relating to the public interest and the proportionality of that measure in relation to the objective pursued. Thus, the measure at issue was considered unjustified <sup>(285)</sup>.

In *Scotch Whisky Association*, the Court considered that increasing the price of the consumption of alcohol in order to pursue the objective of the protection of human life and health by means of imposing a minimum unit price for the retail selling of alcoholic drinks may not be proportionate. This was because less restrictive means, such as increasing excise duties, were available. However, the Court continued by stating that it is for the referring court to determine whether that indeed is the case, having regard to a detailed analysis of all the relevant factors in the case before it. In that regard, the reasons invoked by the Member State by way of justification must be accompanied by appropriate evidence or by an analysis of the appropriateness and proportionality of the restrictive measure adopted, and specific evidence substantiating its arguments <sup>(286)</sup>. The assessment of proportionality is not confined to assessing only the evidence or information available at the time of the adopted measure, but that which is available when the national court gives its ruling <sup>(287)</sup>.

The Member State is also obliged to pursue the stated objectives in a consistent and systematic manner <sup>(288)</sup>. If a Member State can demonstrate that adopting the alternative measure would have a detrimental effect on other legitimate interests, it is taken into consideration in the assessment of proportionality <sup>(289)</sup>. Hence, the proportionality assessment is characterised by the weighing of competing interests within the overall context of the case.

It should be noted that, in the absence of harmonising rules at European level, the Member States are free to decide on the level of protection which they intend to provide for the legitimate interest concerned. In certain areas, the Court has allowed Member States a certain 'margin of discretion' regarding the measures adopted and the level of protection pursued, which may vary from one Member State to another in accordance with their national circumstances. The margin of discretion is quite naturally wider in areas which are considered more sensitive <sup>(290)</sup>.

<sup>(283)</sup> See Case 104/75 *De Peijper* [1976] ECLI:EU:C:1976:67; Case C-54/05 *Commission v Finland* [2007] ECLI:EU:C:2007:168, para. 46 and C-297/05 *Commission v Netherlands* [2007] ECLI:EU:C:2007:53, para. 79, where the Court details available alternatives to the contested measures.

<sup>(284)</sup> Case C-28/09 *Commission v Austria* [2011] ECLI:EU:C:2011:854, para.116-117, 140, 150-151, and Case C-320/03 *Commission v Austria* [2005] ECLI:EU:C:2005:684, para. 87, 91.

<sup>(285)</sup> Case C-549/15 *E.ON Biofor Sverige* [2017] ECLI:EU:C:2017:490, para. 85, 88-99.

<sup>(286)</sup> Case C-333/14 *The Scotch Whisky Association* [2015] ECLI:EU:C:2015:845, para. 50 and 54.

<sup>(287)</sup> Case C-333/14 *Scottish Whiskey Association* [2015] ECLI:EU:C:2015:845, para. 65.

<sup>(288)</sup> See, for instance, Case C-169/07 *Hartlauer* [2009] ECLI:EU:C:2009:141, para. 55 and Case C-333/14 *the Scotch Whisky Association* [2015] ECLI:EU:C:2015:845, par. 37.

<sup>(289)</sup> See Opinion of AG Maduro in Case C-434/04 *Ahokainen and Leppik* [2006] ECLI:EU:C:2006:609, para. 25.

<sup>(290)</sup> It is in particular the case for the objective of protection of health and life of humans, which rank foremost among the assets or interests protected by Article 36 TFEU. This 'margin of discretion' has also been recognised for measures motivated by the necessity to ensure public order, public morality and public security. For examples relating to the public health justification, see Case C-322/01 *DocMorris* [2003] ECLI:EU:C:2003:664, para. 103 and case-law cited. Regarding the public morality justification see Cases 34/79 *Henn and Darby* [1979] ECLI:EU:C:1979:295 and C-244/06 *Dynamic Medien* [2008] ECLI:EU:C:2008:85. Regarding measures in relation to alcohol and justification on grounds of public health and public order see, for instance, Case C-434/04 *Ahokainen and Leppik* [2006] ECLI:EU:C:2006:609. Regarding measures against gambling and justification on grounds of public morality, policy and security, see Case C-65/05 *Commission v Greece* [2006] ECLI:EU:C:2006:673; regarding measures relating to animal protection, see Case C-219/07 *Nationale Raad van Dierenkwekers en Liefhebbers and Andibel* [2008] ECLI:EU:C:2008:353.

Notwithstanding this relative freedom to fix the level of protection pursued, the mere fact that a Member State has opted for a system of protection which differs from that adopted by another Member State cannot affect the assessment of the need for, and proportionality of, the provisions enacted to that end <sup>(291)</sup>. Those provisions must be assessed solely by reference to the objectives pursued by the national authorities of the Member State concerned and the level of protection which they are intended to provide <sup>(292)</sup>.

In light of the increasing number of possible justifications, the proportionality assessment has become an essential and often the defining factor in the Court's reasoning <sup>(293)</sup>.

#### 7.4. Burden of proof

It is for the Member State which claims to have a reason justifying a restriction on the free movement of goods to demonstrate specifically the existence of a reason relating to the public interest, the need for the restriction and the proportionality of the restriction in relation to the objective pursued <sup>(294)</sup>. As explained above, the justification provided by the Member State must be accompanied by appropriate evidence or by an analysis of the appropriateness and proportionality of the restrictive measure adopted, and precise evidence enabling its arguments to be substantiated <sup>(295)</sup>. In this respect, a mere statement that the measure is justified on one of the accepted grounds or the absence of analysis of possible alternatives will be deemed unsatisfactory <sup>(296)</sup>. However, the Court has noted that the burden of proof cannot be so extensive as to require the Member State to prove, positively, that no other conceivable measure could enable that objective to be attained under the same conditions <sup>(297)</sup>.

### 8. RELATIONSHIP TO OTHER FREEDOMS AND ARTICLES OF THE TREATY RELATED TO THE FREE MOVEMENT OF GOODS

#### 8.1. Fundamental freedoms

##### 8.1.1. Article 45 TFEU – Freedom of movement of workers

Article 45 TFEU (ex-Article 39 EC) provides for the freedom of movement for workers within the EU. This freedom entails the abolition of any discrimination based on nationality between EU migrant workers and national workers as regards access to work and working conditions, as well as to tax and social advantages. Article 45 TFEU prohibits not only discrimination based on nationality, but also national rules, which are applicable irrespective of the nationality of the worker concerned but impede their freedom of movement.

Problems related to the movement of workers' personal belongings could theoretically be assessed under Article 34 TFEU or Article 45 TFEU. The Court dealt with this issue in the *Weigel* case <sup>(298)</sup>, which concerned the transfer of a married couple's motor vehicles from their own country (Germany) to the Member State where the husband had taken up employment (Austria). When registering their motor vehicles in Austria, the couple were charged an excessive amount of tax. The couple argued that the tax would deter them from exercising their rights under Article 45 TFEU.

In principle, the Court agreed when it held that '[the tax] is likely to have a negative bearing on the decision of migrant workers to exercise their right to freedom of movement' <sup>(299)</sup>. For other reasons, however, the Court rejected the couple's argument that the tax violated Article 45 TFEU. It is worth noting that the Court did not explicitly answer regarding the question of whether restrictions of such a kind should be treated exclusively under Article 34 TFEU. Moreover, there is still uncertainty over the situations in which it would be more advantageous to apply Article 45 TFEU instead of Article 34 TFEU, bearing in mind that the former provision only applies to nationals of a Member State, whereas Article 34 TFEU applies to products coming from third countries that have been placed in the EU market.

<sup>(291)</sup> See, for instance, Case C-219/07, *Nationale Raad van Dierenkwekers en Liefhebbers and Andibel*, [2008] ECLI:EU:C:2008:353, para. 31.

<sup>(292)</sup> Case C-124/97 *Lääriä and others* [1999] ECLI:EU:C:1999:435, para. 36.

<sup>(293)</sup> See, for instance, Case C-204/12 *Essent Belgium* [2014] ECLI:EU:C:2014:2192, para. 96-116.

<sup>(294)</sup> Case C-14/02 *ATRAL* [2003] ECLI:EU:C:2003:265, para. 69.

<sup>(295)</sup> *Ibid.*, para. 69, Case C-254/05 *Commission v Belgium* [2007] ECLI:EU:C:2007:319, para. 36.

<sup>(296)</sup> Case C-265/06 *Commission v Portugal* [2008] ECLI:EU:C:2008:210, para. 40 to 47.

<sup>(297)</sup> Case C-110/05 *Commission v Italy* [2009] ECLI:EU:C:2009:66, para. 66; Case C-333/14 *Scotch Whiskey Association* [2015] ECLI:EU:C:2015:845, para. 55.

<sup>(298)</sup> Case C-387/01 *Weigel* [2004] ECLI:EU:C:2004:256.

<sup>(299)</sup> *Ibid.*, para. 54.

It should be noted that, according to the case law of the Court, national rules which require the registration and/or taxation of a company vehicle in the Member State where the worker using the vehicle is domiciled, even if the employer who made the vehicle available to the worker is established in another Member State and even if the vehicle is essentially used in the Member State of the employer's establishment, constitute a breach of Article 45 TFEU <sup>(300)</sup>. This is because such provisions may have the effect of preventing a worker from benefiting from certain advantages, such as the provision of a vehicle and ultimately may deter him from working in another Member State at all.

This was confirmed most recently in Case C-420/15, which concerned criminal proceedings brought against an Italian national by Belgian authorities for driving his motor vehicle registered in Italy, on the basis that his principal place of residence was in Belgium. The vehicle was intended essentially for use in Italy and was in use in Belgium only occasionally in order to drive through. The Court confirmed that Article 45 TFEU is to be interpreted as precluding legislation of a Member State which obliges a worker residing there to register a vehicle registered in another Member State and intended essentially for use in that latter State <sup>(301)</sup>.

#### 8.1.2. Articles 49 and 56 TFEU – Freedom to establish and provide services

The freedom of establishment laid down in Article 49 TFEU (ex-Article 43 EC) and the freedom to provide (cross-border) services laid down in Article 56 TFEU (ex-Article 49 EC) are other fundamental freedoms enshrined in the Treaty closely related to the free movement of goods. Both the freedom of establishment and the freedom to provide services refer to self-employed economic activities <sup>(302)</sup>. In the case of establishment the activity in question is performed or the company is founded on a stable and continuous basis and has an indefinite nature <sup>(303)</sup> with an actual or merely potential cross-border dimension <sup>(304)</sup>. By contrast, in the case of cross-border services the activity is performed on a temporary or occasional basis <sup>(305)</sup> and always with a clear cross-border dimension <sup>(306)</sup>.

The performance of self-employed economic activity is common to both freedom of establishment and free provision of services. Because this economic activity consisting of provision of a service (with economic consideration <sup>(307)</sup>) may involve goods, a national measure affecting such a service will also usually affect the circulation of the goods in question. This is clearly the case in distribution of goods, broadly defined as covering transport <sup>(308)</sup> of goods, wholesale and retail <sup>(309)</sup>, but also in case a good is used in performance of the activity, either as equipment or as a material which is an integral part of the service provided. On the other hand, it is clear that free circulation of goods as per Article 34 TFEU includes not only restrictions on the characteristics of the good but also restrictions on its marketing and on its use. The issue of whether to assess a national measure impacting such economic activities under the freedom of establishment /free provision of services or the free movement of goods or both is, therefore, recurrent, and needs to be assessed on a case-by-case basis. For example, restrictions on advertising (e.g. alcohol advertisements <sup>(310)</sup>) may on the one hand affect the promotion sector as service providers, and on the other hand, the effect of such restrictions may relate to specific goods and the market penetration possibilities, and thus may create obstacles to trade in products.

The Court considers that the Treaties do not establish any order of priority between the freedom to provide services and the other fundamental freedoms <sup>(311)</sup>, not even in relation to the freedom to provide services as per Article 57 TFEU which refers to free provision of services as having a subsidiary content in the face of the content of other freedoms <sup>(312)</sup>. Probably

<sup>(300)</sup> Case C-232/01 *Van Lent* [2003] ECLI:EU:C:2003:535 and Case C-464/02 *Commission v Denmark* [2005] ECLI:EU:C:2005:546.

<sup>(301)</sup> Case C-420/15 *U* [2017] ECLI:EU:C:2017:408, paras. 21-22.

<sup>(302)</sup> As opposed to the activity of a worker, under an employment contract, governed by the free movement of workers – see part 7.1 above – see Case C-337/97 *Meeusen* [1999] ECLI:EU:C:1999:284, para. 17 and Case C-413/13 *FNV* [2014] ECLI:EU:C:2014:241, para. 37.

<sup>(303)</sup> Case C-221/89 *Factortame* [1991] ECLI:EU:C:1991:320, para. 20.

<sup>(304)</sup> Case C-384/08 *Attanasio Group* [2010] ECLI:EU:C:2010:133, para. 39.

<sup>(305)</sup> See second subparagraph of Article 57 TFEU and also Case C-55/94 *Gebhard* [1995] ECLI:EU:C:1995:411, para. 39.

<sup>(306)</sup> See first subparagraph of Article 56 TFEU and also Case C-97/98 *Jägerskiöld* [1999] ECLI:EU:C:1999:515, paras. 43 and 44.

<sup>(307)</sup> Meaning normally for remuneration which covers substantially part of the costs of the activity – see Case 263/86 *Humbel* [1988] ECLI:EU:C:1988:451, para. 17.

<sup>(308)</sup> Transport services are not covered by Article 56 TFEU as per Article 58(1) TFEU

<sup>(309)</sup> In Joined Cases C-360/15 and C-31/16 *Visser* [2018] ECLI:EU:C:2018:44, the Court clearly stated that retail activities are a service.

<sup>(310)</sup> Case C-405/98 *Gourmet International Products* [2001] ECLI:EU:C:2001:135.

<sup>(311)</sup> Case C-452/04 *Fidium Finanz* [2006] ECLI:EU:C:2006:631, para. 32.

<sup>(312)</sup> *Ibid.*

for reasons of procedural economy, when a national measure may affect more than one fundamental freedom, the Court has often examined that measure in the light of one fundamental freedom only. For this purpose, it usually decides which of the fundamental freedoms prevails <sup>(313)</sup>. In a few cases it has examined the measure from the viewpoint of both fundamental freedoms.

This can be seen, for instance, in Case C-591/17 *Austria v Germany*, which concerned an infrastructure use charge and a relief from motor vehicle tax for vehicles registered in Germany. The Court concluded that Germany, by introducing the infrastructure use charge for passenger vehicles and by providing, simultaneously, a relief from motor vehicle tax in an amount at least equivalent to the amount of the charge paid, to the benefit of owners of vehicles registered in Germany, failed to fulfil its obligations under Articles 18, 34, 56 and 92 TFEU <sup>(314)</sup>.

*Measures impacting the distribution of a good:* Regarding other measures impacting transport, wholesale and retail of a good, they may simultaneously restrict both the free movement of goods and the freedom to provide distribution services. On the one hand, some measures impacting distribution still clearly belong to the free movement of goods domain such as measures focusing on the act of importing/exporting *per se* (see Section 4.1 above).

Other measures impacting distributive trade services may be *prima facie* presumed to focus on the service of distribution itself rather than on the good being distributed. However, after a case-by-case assessment of the object and more notably of the impact of the measure, the measure may be deemed rather goods-related, when concerning:

- Authorisation schemes for traders (not specifically addressed at importers/exporters) – see Section 4.5 above,
- Obligations for traders to appoint representatives or to provide storage facilities – see Section 4.2 above,
- Price controls and reimbursement obligations – see Sections 4.4 and 4.11 above,
- Advertising restrictions – see Section 4.6 above.

There are also cases where the primary relevance of the measure, in terms of object and impact, cannot be easily assigned to either the goods themselves or the service in question. National provisions which prohibit the auction of goods under certain circumstances may, for example, on the one hand be considered as hampering the service activity of an auctioneer (either established or providing cross-border services), while on the other hand they may create obstacles to the sale of goods <sup>(315)</sup>.

A helpful criterion seems to be the discovery of a significant impact on the making available of the product on the market. Regarding distribution services, the Court's jurisprudence has become clearer over time in this respect, given that many, if not all, of the measures targeting or impacting the distribution of a good have the potential to qualify as 'selling arrangements' as per the Keck jurisprudence (see Section 3.4.2.2 above).

*Measures impacting the use of a good:* Finally, measures targeting and/or impacting goods specifically in relation to their use are often closely related to the performance of a service activity. Therefore, the freedoms of establishment and of free provision of services generally play a prominent role in assessing the admissibility of the measure.

The first aspect to consider is whether the activity implying the use of a good is a self-employed economic activity, i.e., whether it consists of providing services and placing goods on the market with economic consideration. If not, the measure may be deemed to refer to or have a particular impact on the free movement of the good in question, but that measure will not pertain to the freedoms of establishment and of free provision services.

<sup>(313)</sup> Case C-20/03 *Burmanjer* [2005] ECLI:EU:C:2005:307, para. 34.

<sup>(314)</sup> Case C-591/17 *Austria v Germany* [2019] ECLI:EU:C:2019:504, para. 164. In light of the *Visser* judgment (Case C-31/16), the ambit of application of Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market ('Services Directive') (OJ L 376, 27.12.2006, p. 36) is not impacted by the fine separation of the freedoms under the TFEU. When concluding that retail should be considered a service under Article 4(1) of the Services Directive and the Directive's chapter on establishment for providers (Chapter III) applies to internal situations, the Court did not accept that primary law would restrict an interpretation of the Services Directive on its own terms (see paras 92-94 and 107 of the judgment).

<sup>(315)</sup> Case C-239/90 *SCP Boscher* [1991] ECLI:EU:C:1991:180.



However, if the service activity implying the use of a good (in a broad sense, including recycling, reuse or disposal of the good) is a self-employed economic activity, then the measure impacting the use of the good will be relevant for the freedoms of establishment and of free provision of services.

In some cases, the impact on the free circulation of the good in question is not of secondary importance. Here again, a helpful criterion seems to be the discovery of a significant (albeit indirect) impact on the making available of the product on the market <sup>(316)</sup>.

### 8.1.3. Articles 63 TFEU *et seq.* – Free movement of capital and payments

Articles 63 TFEU *et seq.* (ex-Articles 56 EC *et seq.*) regulate the free movement of capital and payments. In particular, Article 63 TFEU prohibits restrictions on the movement of capital and payments between Member States and between Member States and third countries.

The freedom to move certain types of capital is, in practice, a precondition for the effective exercise of other freedoms guaranteed by the TFEU <sup>(317)</sup>.

Despite the fact that the points of contact with the free movement of goods are limited, the EU Court of Justice has long since made it clear that means of payment are not to be regarded as goods <sup>(318)</sup>. Furthermore, the EU Court of Justice ascertained that a material transfer of assets must be regarded as a movement of capital within the meaning of Article 63(1) TFEU, or – where such a transfer constitutes a payment connected with trade in goods or services – a payment within the meaning of Article 63(2) TFEU <sup>(319)</sup>.

While cross-border capital movements may regularly involve the investment of funds <sup>(320)</sup>, it cannot be excluded that under specific circumstances they may also concern transfers in kind. The EU Court of Justice has held that, where a taxpayer of a Member State seeks the deduction for tax purposes of a sum reflecting the value of gifts to third persons who are residents in another Member State, it does not matter whether the underlying gifts were made in money or in kind. Such gifts come within the compass of Article 63 TFEU as well, even if they are made in kind in the form of everyday consumer goods <sup>(321)</sup>.

In addition, the Court has also dealt with issues of car registration from the perspective of Article 63 TFEU, too <sup>(322)</sup>. Though typically treated as a barrier to the free movement of goods if this procedure restricts the circulation of certain vehicles between Member States, the Court has made an assessment in terms of the free movement of capital where a vehicle has been loaned free of charge in a cross-border transaction between citizens in different Member States <sup>(323)</sup>.

## 8.2. Other relevant Treaty articles

### 8.2.1. Article 18 TFEU – Non-discrimination based on nationality

Article 18 TFEU (ex-Article 12 EC) prohibits discrimination on grounds of nationality. It is settled in case law that the provision is only intended to apply independently to situations governed by EU law where no specific rules on non-discrimination are laid down <sup>(324)</sup>.

The principle of non-discrimination on grounds of nationality as enshrined in Article 18 TFEU finds specific expression in the Treaty's provisions on the free movement of persons, amongst which, the free movement of workers provided for under Article 45 TFEU and the freedom to provide services under Article 56 TFEU. In *Austria v Germany*, however, the Court

<sup>(316)</sup> The (direct) impact of the measure on the use may be such as to determine that goods not being able to conform with such particular use, although legally sold on the market, shall have their demand severely restricted or even wiped out.

<sup>(317)</sup> Case 203/80 *Casati* [1981] ECLI:EU:C:1981:261, para. 8.

<sup>(318)</sup> Case 7/78 *Thompson* [1978] ECLI:EU:C:1978:209, para. 25.

<sup>(319)</sup> Case C-358/93 *Bordessa and Others* [1995] ECLI:EU:C:1995:54, para. 13-14.

<sup>(320)</sup> Although the Treaty does not define the terms 'movements of capital' and 'payments', it is settled case-law that Council Directive 88/361/EEC of 24 June 1988 for the implementation of Article 67 of the Treaty (OJ L 178, 8.7.1988, p. 5), together with the nomenclature annexed to it, may be used for the purposes of defining what constitutes a capital movement (Case C-222/97 *Trummer and Mayer* [1999] ECLI:EU:C:1999:143, paras 20 and 21).

<sup>(321)</sup> Case C-318/07 *Persche* [2009] ECLI:EU:C:2009:33, paras. 25 and 30.

<sup>(322)</sup> See section 4.2.

<sup>(323)</sup> Case C-583/14 *Nagy* [2015] ECLI:EU:C:2015:737, para. 23.

<sup>(324)</sup> Case C-591/17 *Austria v Germany* [2019] ECLI:EU:C:2019:504, para. 39; Case C-296/15 *Medisanus* [2017] EU:C:2017:431.

considered a motorway-financing scheme in light of Article 18 as well as Articles 34, 56 and 92 TFEU. The German national fiscal measure was ultimately found to be in violation of all of these treaty obligations, as the financial burden of a new charge under the scheme would rest solely on the owners of foreign vehicles <sup>(325)</sup>.

### 8.2.2. Articles 28 and 30 TFEU – The customs union

While Article 34 TFEU covers non-tariff trade barriers, all customs duties and charges having equivalent effect are prohibited under Articles 28 and 30 TFEU (ex-Article 25 EC). This prohibition is of a general and absolute nature. It applies to all customs duties or charges with equivalent effect amongst Member States, irrespective of their amount, designation, mode of application or the purpose and the destination of the revenue generated <sup>(326)</sup>.

Unlike Article 34 TFEU, Articles 28 and 30 TFEU do not allow for derogations <sup>(327)</sup>. However, charges levied for inspections carried out for complying with obligations imposed by EU law and charges representing a proportionate payment for a service actually provided would escape the application of Article 30 TFEU <sup>(328)</sup>.

Articles 28 and 30 TFEU should be distinguished from the prohibition of discriminatory internal taxation contained in Article 110 TFEU, which can be subject to justifications. It should always be considered that Articles 30 and 110 TFEU are mutually exclusive <sup>(329)</sup>.

Charges having equivalent effect to customs duties under Article 30 TFEU are imposed unilaterally on goods because of the fact that they cross a frontier <sup>(330)</sup>. However, national measures introducing the same levy on domestic goods and identical exported goods at the same marketing stage where the chargeable event triggering the levy is identical, would be covered by Article 110 TFEU <sup>(331)</sup>. Exceptionally, where the burden borne by a national product is fully offset by the advantages from that charge, such charge would fall under Articles 28 and 30 TFEU <sup>(332)</sup>.

Finally, the Court has clarified that the taxpayer should be able to obtain the reimbursement of a charge contrary to Article 30 TFEU even in a situation where the payment mechanism for the charge has been designed in national legislation so that the charge is passed on to the consumer <sup>(333)</sup>.

### 8.2.3. Article 37 TFEU – State monopolies

According to the first paragraph of Article 37 TFEU (ex-Article 31 EC), 'Member States shall adjust any State monopolies of a commercial character so as to ensure that no discrimination regarding the conditions under which goods are procured and marketed exists between nationals of Member States'.

This does not mean that the monopolies have to be lifted, but it means that they have to be adjusted in such a way as to eliminate their possible discriminative effect. Generally speaking, Article 37 TFEU applies in circumstances where the State: (1) grants exclusive purchase or sales rights and thus enables the control of imports or exports, and (2) grants rights to a state enterprise, a state institution or, by means of delegation, to a private organisation.

<sup>(325)</sup> Case C-591/17 *Austria v Germany* [2019] ECLI:EU:C:2019:504, para. 162-164.

<sup>(326)</sup> Case 24/68 *Commission v Italy* [1969] ECLI:EU:C:1969:29 para.7; C-441/98 *Michailidis* [2000] ECLI:EU:C:2000:479, para. 15; Case C-313/05 *Brzeziński* [2007] ECLI:EU:C:2007:33, para.22, Case C-254/13 *Orgacom* [2014] ECLI:EU:C:2014:2251, para. 23; Case C-65/16 *Istanbul Logistik* [2017] ECLI:EU:C:2017:770, para. 39.

<sup>(327)</sup> Case C-173/05 *Commission v Italy*, [2007], ECLI:EU:C:2007:362, para.42, Case C-65/16 *Istanbul Logistik*, [2017] ECLI:EU:C:2017:770, para.40, Case C-305/17, *FENS* [2018] ECLI:EU:C:2018:986, para. 53.

<sup>(328)</sup> Joined Cases C-149/91 and C-150/91, *Sanders Adour and Guyomarc'h Orthez Nutrition animale*, [1992] ECLI:EU:C:1992:261, para. 17, Case C-72/03 *Carbonati Apuani* [2004] ECLI:EU:C:2004:506, para 31 and Case C-39/17 *Lubrizol* [2018] ECLI:EU:C:2018:438, para. 26.

<sup>(329)</sup> Case C-39/17 *Lubrizol* [2018] ECLI:EU:C:2018:438, para. 25.

<sup>(330)</sup> Case 24/68 *Commission v Italy* [1969] ECLI:EU:C:1969:29 para. 14; C-441/98 *Michailidis* [2000] ECLI:EU:C:2000:479, para. 15, Case C-313/05 *Brzeziński* [2007] ECLI:EU:C:2007:33, para.22, Case C-254/13 *Orgacom*, ECLI:EU:C:2014:2251, para. 23, Case C-65/16 *Istanbul Logistik* ECLI:EU:C:2017:770, para. 39.

<sup>(331)</sup> Case C-254/13 *Orgacom* [2014] ECLI:EU:C:2014:2251, para. 29.

<sup>(332)</sup> Case C-28/96 *Fricarnes* [1997] ECLI:EU:C:1997:412, paras. 24 and 25. Case C-76/17, *Petrotel-Lukoil and Georgescu* [2018] ECLI:EU:C:2018:139, para. 24.

<sup>(333)</sup> Case C-76/17 *Petrotel-Lukoil and Georgescu* [2018] ECLI:EU:C:2018:139, para. 39.

Article 37 TFEU has a direct effect and it only applies to goods (hence, it does not cover the free movement of services or capital<sup>(334)</sup>). Moreover, the Treaty provision concerns activities intrinsically connected with the specific business of the monopoly and it is thus irrelevant to national provisions which do not have this connection. This approach suggests that Article 37 TFEU constitutes a *lex specialis* vis-à-vis the general provision of Article 34 TFEU. In the *Franzén* case concerning the Swedish alcohol retail monopoly, the Court held that ‘rules relating to the existence and operation of the monopoly’<sup>(335)</sup> fall under Article 37 TFEU, whereas ‘other provisions of the domestic legislation which are separable from the operation of the monopoly although they have a bearing upon it, must be examined with reference to [Article 34 TFEU]’<sup>(336)</sup>.

In the *Hanner* case relating to the Swedish pharmaceuticals retail monopoly, the Court argued that Article 37 TFEU ‘aims at the elimination of obstacles to the free movement of goods, save, however, for restrictions on trade which are inherent in the existence of the monopolies in question’<sup>(337)</sup>. Subsequently, the Court explained in the *Rosengren* case that ‘While [...] the measure at issue in the main proceedings affects the free movement of goods within the European Community, it does not, as such, govern the [Swedish alcohol retail] monopoly’s exercise of its exclusive right of retail sale of alcoholic beverages on Swedish territory. That measure, which does not, therefore, concern the monopoly’s exercise of its specific function, accordingly cannot be considered to relate to the very existence of that monopoly’<sup>(338)</sup>.

This line of reasoning has been repeated in more recent case law, such as in the *ANETT* case, which concerns national legislation that imposes prohibitions on tobacco retailers from importing tobacco products from other Member States. First, the Court stated that Article 37 TFEU is applicable if the legislation in question concerns the operation of a monopoly of a commercial character and gives rise to restrictions on trade which are inherent in the existence of such a monopoly. Second, it stated that the rules relating to the existence and the operation of a monopoly must be examined in light of the provisions of Article 37 TFEU, which are specifically applicable to the exercise of the monopoly’s exclusive rights. In turn, provisions of domestic legislation, which are separable from the operation of the monopoly although they have a bearing upon it, must be examined in the light of Article 34 TFEU.<sup>(339)</sup>

In *ANETT*, the Court held that because the specific purpose of the monopoly in question was to reserve the exclusive right for the sale of tobacco products at retail level to authorised retailers, the prohibition affected the free movement of goods and did not govern the exercise of the exclusive right relating to the monopoly. Such a prohibition was considered separable from the operation of the monopoly, as it related not to the selling arrangements for retail sale of tobacco products, but to the upstream market of such products. Likewise, the prohibition did not target either the sale network of the monopoly or the marketing or advertising of the products distributed by it. The Court concluded that because the national measure could not be regarded as a rule relating to the existence or the operation of the monopoly, Article 37 TFEU was irrelevant for the purposes of determining whether such a prohibition is compatible with EU law<sup>(340)</sup>.

In *Visnapuu*, the Court assessed whether the retail sale licence required for the importation of alcoholic beverages with a view to their retail sale to consumers residing in Finland must be assessed in the light of Article 34 TFEU or Article 37 TFEU. According to the Finnish Government, the monopoly system should be assessed in the light of Article 37 TFEU and the licencing scheme in the light of Article 34 TFEU. The Court agreed and stated that the licencing schemes do not govern the operation of the monopoly or the exercise of its exclusive rights, since they provide that duly authorised persons may engage in the retail sale of certain categories of alcoholic beverages. Accordingly, those licencing schemes are separable from the operation of the monopoly and must be examined in the light of Article 34 TFEU<sup>(341)</sup>. In line with *Franzén*, the Court reminded that Article 37 TFEU requires that the monopoly is arranged in such a manner which excludes any discrimination between Member States as regards to the conditions under which goods are procured and marketed, so that trade in goods from other Member States is not put at a disadvantage and that competition between the economies of the Member States is not distorted<sup>(342)</sup>.

<sup>(334)</sup> Case 155/73 *Sacchi* [1974] ECLI:EU:C:1974:40.

<sup>(335)</sup> Case C-189/95 *Franzén* [1997] ECLI:EU:C:1997:504, para. 35.

<sup>(336)</sup> Case C-189/95 *Franzén* [1997] ECLI:EU:C:1997:504, para. 36.

<sup>(337)</sup> Case C-438/02 *Hanner* [2005] ECLI:EU:C:2005:332, para. 35.

<sup>(338)</sup> Case C-170/04 *Rosengren* [2007] ECLI:EU:C:2007:313, para. 21-22; see also Case C-186/05 *Commission v Sweden* [2007] ECLI:EU:C:2007:571.

<sup>(339)</sup> Case C-456/10 *ANETT* [2012] ECLI:EU:C:2012:241, para. 21-23.

<sup>(340)</sup> Case C-456/10 *ANETT* [2012] ECLI:EU:C:2012:241, para. 25-31.

<sup>(341)</sup> Case C-198/14 *Visnapuu* [2015] ECLI:EU:C:2015:751, para. 90-91.

<sup>(342)</sup> Case C-198/14 *Visnapuu* [2015] ECLI:EU:C:2015:751, para. 95.

In light of the case law, the Court seems to have opted to consider Articles 34 and 37 TFEU as mutually exclusive. In case the national measure at issue does not concern the exercise of the specific purpose of the monopoly, it falls outside the scope of Article 37 TFEU and is to be assessed under Articles 34 and 36 TFEU.

On the other hand, it may also be argued that there is some overlap between Article 37 TFEU and other Treaty articles. The Court has held in infringement cases concerning different national electricity and gas monopolies<sup>(343)</sup> that a joint application of Articles 37 and 34 TFEU is indeed possible. Such an approach would mean that a measure related to a state monopoly would first have to be examined under Article 37 TFEU. If the measure is considered discriminatory, examination under Articles 34 and 35 TFEU will no longer be necessary. Conversely, if it is concluded that the measure is not discriminatory according to Article 37 TFEU, it will be necessary to examine it under the general provisions on the free movement of goods.

#### 8.2.4. Article 107 TFEU – State aids

Article 107 TFEU (ex-Article 87 EC) provides that any aid granted by a Member State or through state resources in any form whatsoever which distorts or threatens to distort competition by favouring certain undertakings or the production of certain goods is, in so far as it affects trade between Member States, incompatible with the internal market.

In this respect the State aid rules and Articles 34-36 TFEU serve a common purpose, namely to ensure the free movement of goods between Member States under normal conditions of competition<sup>(344)</sup>. However, as their focal point is different, the qualification of a State measure as State aid does not automatically preclude the scrutiny of an aid scheme in relation to other EU rules, such as Articles 34-36 TFEU<sup>(345)</sup>. In the landmark case *Commission v France*<sup>(346)</sup>, for instance, the EU Court of Justice examined the legality of a measure that gave newspaper publishers tax exemptions on the condition that the papers were printed in France. While the Commission argued that this constituted a breach of Article 34 TFEU, the French Government argued that the measure should have been considered according to Article 107 TFEU, since the tax provisions could not be separated from the general aid scheme for the newspaper industry. The Court, noticing that France had not notified the aid in accordance with Article 108(3) TFEU, issued the following statement of principle ‘the mere fact that a national measure may possibly be defined as aid [...] is not an adequate reason for exempting it’ under the free movement of goods’ provisions<sup>(347)</sup>. Furthermore, in the preliminary ruling of *PreussenElektra*<sup>(348)</sup>, the Court found that the national measure related to the regional electricity supply could have been capable – at least potentially – of hindering intra-community trade. However, since the measure was aimed at protecting the environment by contributing to the reduction of emission of greenhouse gases, it was not considered contrary to the free movement of goods.

At the same time, the mere fact that a State aid measure as such affects intra-EU trade is in itself not sufficient to qualify the measure simultaneously as a measure having equivalent effect under Article 34 TFEU. Instead, the Court differentiates between aspects that are indissolubly linked to the objective of the aid and aspects that can be separated from conditions and actions which, even though they form part of the aid scheme, may be regarded as not being necessary for the attainment of the purpose of the aid or its proper functioning<sup>(349)</sup>. Only the latter aspects are covered by Articles 34-36 TFEU. As stated by the General Court in *Castelnuovo Energia, SL*<sup>(350)</sup> ‘the fact that a system of aids provided by the State or by means of State resources may, simply because it benefits certain national undertakings or products, hinder, at least indirectly, the importation of similar or competing products coming from other Member States, is not in itself sufficient to put an aid as such on the same footing as a measure having an effect equivalent to a quantitative restriction within the meaning of Article 34 TFEU’.

<sup>(343)</sup> Cases C-159/94 *Commission v France* [1997] ECLI:EU:C:1997:501, para. 41; C-158/94 *Commission v Italy* [1997] ECLI:EU:C:1997:500, para. 33; C-157/94 *Commission v The Netherlands* [1997] ECLI:EU:C:1997:499, para. 24.

<sup>(344)</sup> Case 103/84 *Commission v Italy* [1986] ECLI:EU:C:1986:229, para. 19.

<sup>(345)</sup> Case C-234/99 *Nygård* [2002] ECLI:EU:C:2002:244, para. 56; Case 351/88 *Laboratori Bruneau* [1991] ECLI:EU:C:1991:304, para. 7.

<sup>(346)</sup> Case 18/84 *Commission v France* [1985] ECLI:EU:C:1985:175.

<sup>(347)</sup> Case 21/88 *Du Pont de Nemours Italiana Spa* [1990] ECLI:EU:C:1990:121; Case 351/88 *Laboratori Bruneau Srl* [1991] ECLI:EU:C:1991:304; C-156/98 *Germany* [2000] ECLI:EU:C:2000:467, para. 78 and Case C-114/00 *Spain v Commission* [2002] ECLI:EU:C:2002:508, para. 104.

<sup>(348)</sup> Case C-379/98 *PreussenElektra* [2001] ECLI:EU:C:2001:160.

<sup>(349)</sup> Case 74/76 *Ianelli* [1977] ECLI:EU:C:1977:51, para. 17.

<sup>(350)</sup> Case T-57/11 *Castelnuovo Energia v Commission* [2014] ECLI:EU:T:2014:1021, para. 196.

From the case law it is also clear that a national court has competence to assess whether an aid scheme complies with Treaty provisions which have direct effect other than those relating to State aids (e.g. Articles 34 to 36 TFEU; 63 TFEU <sup>(351)</sup>), only if the provisions can be evaluated separately and are not necessary for the attainment of the objective or the functioning of the aid scheme <sup>(352)</sup>. Consequently, Articles 107 and 108 TFEU preclude a national court from carrying out an assessment of a State measure under other direct effect provisions, insofar as the latter are linked to the functioning and the object of the measure at stake.

#### 8.2.5. Article 110 TFEU – Tax provisions

Article 110 TFEU (ex-Article 90 EC) supplements the provisions on the abolition of customs duties and charges having equivalent effect. Its aim is to ensure free movement of goods between the Member States in normal conditions of competition by eliminating all forms of protection which may result from the application of internal taxation that discriminates against products from other Member States <sup>(353)</sup>. In relation to Article 34 TFEU, Article 110 is considered as *lex specialis*, which means that cases covered by Article 110 exclude the application of Article 34 TFEU. This was the case in the *Kawala* <sup>(354)</sup> judgment, where the Court decided that a registration fee for imported second-hand vehicles, being of a fiscal nature, falls under Article 110 TFEU and that therefore Article 34 TFEU is not applicable. However, it should be recalled that, according to settled case law, the Member States must exercise their competence in the area of direct taxation in a way that is compatible with EU law and, in particular, with the fundamental freedoms guaranteed by the Treaty <sup>(355)</sup>.

The first paragraph of Article 110 TFEU prohibits all Member States from imposing on products of the other Member States internal taxation in excess of that imposed on similar domestic products. This provision is infringed where the tax charged on an imported product and that charged on a similar domestic product are calculated differently on the basis of different criteria which lead, even if only in certain cases, to higher taxation being imposed on the imported product.

The Court defined similar products as those which have similar characteristics and meet the same needs from the point of view of consumers, the test being not whether they are strictly identical but whether their use is similar and comparable. In *Commission v France* <sup>(356)</sup>, the Court considered that dark- and light-tobacco cigarettes could be regarded as similar products.

Practical difficulties cannot be used to justify the application of internal taxation which discriminates against products from other Member States <sup>(357)</sup>.

The second paragraph of Article 110 TFEU is intended to prevent any form of indirect fiscal protectionism affecting products from other Member States which although not similar to domestic goods, nevertheless compete with some of them. The higher taxation of products from other Member States compared with competing domestic goods is prohibited when it is such as to have the effect, on the market in question, of reducing potential consumption of imported products to the advantage of competing domestic products. In *Commission v Sweden* <sup>(358)</sup>, the Court considered that wines in the intermediate category (mainly imported) shared a sufficient number of characteristics with strong beer (mainly domestic) to be regarded as being in competition with strong beer. However, the Court considered in this case that there was no proof that the difference in the tax treatment of those two products was liable to influence consumer behaviour in the sector concerned (no protective effect).

In cases where a charge is levied on domestic and imported products and the receipts are intended to finance activities which benefit only the domestic products, thus partially <sup>(359)</sup> offsetting the tax burden borne by the latter goods, such a charge constitutes discriminatory taxation prohibited by Article 110 TFEU <sup>(360)</sup>.

<sup>(351)</sup> Case C-598/17 *A-Fonds* [2019] ECLI:EU:C:2019:352.

<sup>(352)</sup> *Ibid.*, para. 47. To that effect, see also C-234/99 *Nygård* [2002] ECLI:EU:C:2002:244, para. 57.

<sup>(353)</sup> Case C-91/18 *Commission v Greece* [2019] ECLI:EU:C:2019:600 para. 52.

<sup>(354)</sup> Case C-134/07 *Piotr Kawala v Gmina Miasta Jaworzna* [2007] ECLI:EU:C:2007:770.

<sup>(355)</sup> See, for instance, Case C-591/17 *Austria v Germany* [2019] ECLI:EU:C:2019:504, para. 56 and the case-law cited.

<sup>(356)</sup> Case C-302/00 *Commission v France* [2002] ECLI:EU:C:2002:123.

<sup>(357)</sup> Case C-221/06 *Stadtgemeinde Frohnleiten* [2007] ECLI:EU:C:2007:185, para. 70.

<sup>(358)</sup> Case C-167/05, *Commission v Sweden* [2008] ECLI:EU:C:2008:202.

<sup>(359)</sup> In case of full offsetting, that charge constitutes a charge having an effect equivalent to a customs duty, contrary to Article 28 and 30 TFEU.

<sup>(360)</sup> Case C-76/17 *Petrotel-Lukoil* [2018] ECLI:EU:C:2018:139, paras. 22 -25.

### 8.2.6. Article 351 TFEU

Article 351 TFEU (ex-Article 307 EC) refers to the rights and obligations under international law entered into by the Member States before 1958, or before the date of their accession with one or more third countries. The rule is that these rights and obligations shall not be affected by the provisions of the Treaty provided that the following cumulative conditions are met:

- The international agreement **must require and not merely allow** the Member State to adopt a measure that is incompatible with an obligation of that Member State under Union law. In relation to Article 34 TFEU the Court mapped, in Case C-324/93 <sup>(361)</sup>, the boundaries of the Member States' possibilities for adopting measures which contravene their obligations under that article. The problem concerned refusal to grant a licence to import diamorphine (a narcotic drug subject to the 1961 Single Convention on Narcotic Drugs) into the United Kingdom. The Court ruled that the fact that a measure 'may have been adopted under an international agreement predating the Treaty or accession by a Member State and that the Member State maintains the measure pursuant to Article [351], despite the fact that it constitutes a barrier, does not remove it from the scope of Article [34], since Article [351] takes effect only if the agreement imposes on a Member State an obligation that is incompatible with the Treaty'.

The conclusion is that Member States must refrain from adopting measures which contravene EU law, in particular the rules on the free movement of goods, when the international agreements to which they are signatory do not require them to adopt such measures.

- The agreement does not challenge the principles that form part of the very foundations of the Union legal order.

## 9. ENFORCEMENT OF ARTICLES 34 AND 35 TFEU

### 9.1. Direct effect – private enforcement

The Court of Justice has recognised that the prohibition laid down in Article 34 TFEU is 'mandatory and explicit and its implementation does not require any subsequent intervention of the Member States or [Union] institutions'. Therefore, Article 34 TFEU has 'direct effect and creates individual rights which national courts must protect' <sup>(362)</sup>.

Later the Court ruled that Article 35 TFEU also has direct effect and that its provisions are likewise 'directly applicable' and 'confer on individuals rights which courts of Member States must protect' <sup>(363)</sup>.

Individuals can invoke the principle of and right to the free movement of goods by bringing a case before a national court. The latter may refuse to apply any national rule which it considers to be contrary to Articles 34 and 35 TFEU. National courts may also have to evaluate to what extent an obstacle to imports or exports may be justified in terms of mandatory requirements or public interest objectives listed in Article 36 TFEU.

### 9.2. SOLVIT

SOLVIT is a network ([www.europa.eu/solvit](http://www.europa.eu/solvit)) that aims at solving problems caused by the misapplication of internal market law by public authorities <sup>(364)</sup>. For this purpose, all EEA Member States have set up their own SOLVIT centres, which communicate directly via an online database. The SOLVIT centres are part of the national administration and they are devoted to providing solutions to problems for both citizens and businesses within a ten-week period. A 2001 Commission recommendation <sup>(365)</sup> approved by the Council sets out the rules of procedure within SOLVIT. The European Commission supervises the network and, if needed, assists in speeding up the resolution of complaints. In 2018, SOLVIT handled more than 2 000 cases with a resolution rates in that year standing at 90 %.

<sup>(361)</sup> Case C-324/93 *The Queen v Secretary of State for Home Department, ex parte Evans Medical and Macfarlan Smith* [1995] ECLI:EU:C:1995:84.

<sup>(362)</sup> Case 74/76 *Iannelli v Meroni* [1977] ECLI:EU:C:1977:51.

<sup>(363)</sup> Case 83/78 *Pigs Marketing Board v Redmond* [1978] ECLI:EU:C:1978:214.

<sup>(364)</sup> Additional information in Communication of Commission: Action plan on the reinforcement of SOLVIT (COM(2017) 255) and Commission Recommendation on the principles governing SOLVIT (C(2013) 5869).

<sup>(365)</sup> Commission Recommendation of 7 December 2001 on principles for using 'SOLVIT' – the Internal Market Problem Solving Network (C(2001) 3901) (OJ L 331, 15.12.2001, p. 79).

In addition, a new problem-solving procedure related to SOLVIT was introduced by Regulation (EU) 2019/515 on mutual recognition. Article 8 of the Regulation sets out a procedure applying to cases where national authorities have issued an administrative decision. It is possible for the SOLVIT centre involved in this procedure to request the Commission to assess the compatibility of an administrative decision and issue an opinion. This procedure entails longer deadlines than the usual SOLVIT procedure.

### 9.3. Infringement proceedings under Articles 258 and 260 TFEU

#### 9.3.1. Infringement procedure

In its role as 'the guardian of the Treaty', the Commission might, acting upon a complaint or on its own initiative, start infringement proceedings against a Member State which is deemed to have failed to comply with its obligations in relation to EU law.

Article 258 TFEU (ex-Article 226 EC) provides for the formal steps of the infringement procedure. The first stage is the sending of a Letter of Formal Notice to the Member State concerned, requesting it to submit its observations by a specified date, usually within two months.

In light of the reply or absence thereof, the Commission may decide to address a Reasoned Opinion to the Member State. The Reasoned opinion sets out why the Commission considers that there has been an infringement of EU law, and calls upon the Member State to comply with EU law by a specified date, usually within two months. If the Member State fails to comply with the EU law, the Commission may decide to refer the case to the EU Court of Justice in order to obtain a declaration that EU law has been infringed.

The Letter of Formal Notice and the Reasoned Opinion issued by the Commission delimit the subject matter of the dispute, so that it cannot thereafter be extended. Consequently, the Reasoned Opinion and the proceedings brought by the Commission must be based on the same grounds as those set out in the letter of formal notice initiating the pre-litigation procedure <sup>(366)</sup>.

Where the Court finds in its final ruling on the issue that EU law has been infringed, the Member State concerned is required to take the measures necessary to comply with the judgment. If the infringement persists, the Commission might again refer the case to the Court and ask for the application of financial sanctions (lump sum and daily penalty payment). The procedure for the second referral to the Court is laid down in Article 260(2) TFEU. Under this procedure and as long as the Member State has not complied with the Court judgment, the Commission (1) sends a letter to the Member State on its obligation to comply; (2) then sends a Letter of Formal Notice; and finally (3) may refer the matter to the Court (second referral). If the Court of Justice finds that the Member State concerned has not complied with its first judgment, it may impose financial sanctions. These financial sanctions are intended to have a deterrent effect and to encourage Member States to comply with EU law as rapidly as possible <sup>(367)</sup>.

#### 9.3.2. Complaints

Anyone considering that a measure by a Member State is contrary to Articles 34-36 TFEU may file a complaint with the European Commission. As a matter of fact, a large proportion of infringement procedures relating to the free movement of goods are initiated by the Commission following a complaint. Successive Commission communications on relations with the complainant in respect of infringements of EU law <sup>(368)</sup> lay down the rules on the handling of complaints.

<sup>(366)</sup> Case C-457/07 *Commission v Portugal* [2009] ECLI:EU:C:2009:531, para. 55.

<sup>(367)</sup> For more information on the infringement procedure and the method for calculating financial sanctions, see: [https://ec.europa.eu/info/law/law-making-process/applying-eu-law/infringement-procedure\\_en](https://ec.europa.eu/info/law/law-making-process/applying-eu-law/infringement-procedure_en)

<sup>(368)</sup> Commission communication to the European Parliament and the European ombudsman on relations with the complainant in respect of infringements of community law (COM(2002) 141 final). Communication from the Commission to the Council and the European Parliament. Updating the handling of relations with the complainant in respect of the application of Union law (COM(2012) 154 final). Communication from the Commission – EU law: Better results through better application (C(2016) 8600) (OJ C 18, 19.1.2017, p. 10).

Complaints are submitted by using a standard complaint form. The complaint form is available from the Commission on request or online from the Europa website <sup>(369)</sup>. Complaints must be submitted online, or in writing by letter to the Commission Secretariat-General at the address '1049 Brussels, Belgium' or lodged with one of the Commission's offices in the Member States. The standard complaint form can be submitted in on line or sent by post in any of the official languages of the EU.

An initial acknowledgement of receipt will be sent to the complainant by the Commission within 15 working days. Within one month of this acknowledgement, the Commission will decide whether the submitted complaint should be registered.

While the complainant is not a formal party to any procedure initiated against a Member State, it is worth noting that he/she enjoys some important administrative rights:

- The Commission will not disclose his/her identity unless he/she has expressly agreed to the disclosure.
- The Commission will endeavour to take a decision on the substance (either to open infringement proceedings or to close the case) within twelve months of registration of the complaint.
- The Commission will keep the complainant informed of the main steps in the process. He/she will be notified in advance by the relevant Commission service if it plans to close the case, enabling him/her to react by providing new facts or elements.
- If, after investigation, the Commission considers that there may indeed be an infringement of EU law, it may decide to initiate infringement proceedings under Article 258 TFEU.

As guardian of the Treaty, the Commission is very vigilant in ensuring overall compliance with EU law and in monitoring Member States' adherence to the rules and obligations set out in the Treaty or secondary legislation. However, for different reasons, legal procedures such as infringement proceedings under Article 258 TFEU may not always provide the best available means to address a particular issue. It is therefore important to emphasise that the Commission, even if it is fully committed to its role of supervising the observance of EU law by Member States, enjoys a wide margin of discretion on whether or not to open infringement proceedings <sup>(370)</sup>.

## 10. RELATED INSTRUMENTS OF SECONDARY LAW

### 10.1. **Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services** <sup>(371)</sup>

Directive (EU) 2015/1535 obliges the Member States of the European Union to notify the Commission and their counterparts of any draft technical regulations relating to goods or to information society services before they are adopted. EEA countries, Switzerland and Turkey also notify their technical regulations under Technical Regulation Information System (TRIS).

The Commission and the Member States operate via a system of preventive control. During standstill periods, the Member States must refrain from adopting their notified draft regulations for at least three months while they are being examined. During this period, a bilateral discussion with the authorities of the Member States may be held. If the draft regulation is found in breach of EU internal market law, the standstill period can be extended up to six months. An extension up to 18 months can even be imposed by a blocking decision if the Council adopts a position on the same matter covered by the notified draft regulation <sup>(372)</sup>.

<sup>(369)</sup> [https://ec.europa.eu/assets/sg/report-a-breach/complaints\\_en/](https://ec.europa.eu/assets/sg/report-a-breach/complaints_en/); [https://ec.europa.eu/info/about-european-commission/contact/problems-and-complaints/complaints-about-breaches-eu-law/how-make-complaint-eu-level\\_en#submitting-a-complaint-online](https://ec.europa.eu/info/about-european-commission/contact/problems-and-complaints/complaints-about-breaches-eu-law/how-make-complaint-eu-level_en#submitting-a-complaint-online)

<sup>(370)</sup> Case 200/88 *Commission v Greece* [1990] ECLI:EU:C:1990:346; Order in Case T-47/96 [1996] ECLI:EU:T:1996:164, para. 42; see as well order in Case T-177/05 *Finland v Commission* of 9 January 2006, para. 37-40.

<sup>(371)</sup> OJ L 241, 17.9.2015, p. 1.

<sup>(372)</sup> See Articles 5-6 of the Directive.



The procedure therefore aims at eliminating any obstacles to the smooth functioning of the internal market before they even appear, thus avoiding corrective action, which is always more burdensome.

According to the case law of the Court of Justice (see judgments *CIA Security* and *Unilever* <sup>(373)</sup>), any technical regulation which has not been notified at the draft stage or has been adopted during the mandatory standstill period cannot be applied and thus enforced by national tribunals against individuals. This has subsequently been confirmed by the Court <sup>(374)</sup>.

#### 10.2. Regulation (EU) 2019/515 – The ‘Mutual Recognition’ Regulation

In 2008, the EU legislator adopted the Regulation (EC) No 764/2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State. The main objective of this Regulation was to define the rights and obligations of national authorities and businesses when the former intend to refuse market access of a product lawfully marketed in another Member State. The Regulation placed the burden of proof on the national authorities that intend to deny market access requiring them to indicate the technical or scientific reason for their intention to deny the product access to the national market. The economic operator was given the opportunity to defend his case and to submit solid arguments to the competent authorities.

The Regulation also established ‘Product Contact Points’ in each Member State, which provide information about technical rules on products and the implementation of the mutual recognition principle to enterprises and competent authorities in other Member States.

Regulation (EU) 2019/515 on the mutual recognition of goods lawfully marketed in another Member State repealed Regulation (EC) No 764/2008 as from 19 April 2020.

Regulation (EU) 2019/515 intends to improve legal certainty for businesses and national authorities. It introduces the mutual recognition declaration (self-declaration) for economic operators to demonstrate that goods were lawfully marketed in another Member State, establishes a new problem solving procedure building up on SOLVIT and provides for closer administrative cooperation and a common IT tool to enhance communication, cooperation and trust among national authorities.

A separate guidance document explains in more detail Regulation (EU) 2019/515.

#### 10.3. Regulation (EC) No 2679/98 – The ‘strawberry’ Regulation

Council Regulation (EC) No 2679/98 on the functioning of the internal market in relation to the free movement of goods among the Member States <sup>(375)</sup> provides for special procedures to cope with serious obstacles to the free movement of goods among Member States which cause heavy loss to the individuals affected and require immediate action. Those obstacles may, for example, be the result of passivity of national authorities in the face of violent action by individuals or non-violent blockages of borders, or of action by a Member State, such as an institutionalised boycott of imported products.

The Regulation provides for an alert procedure and for the exchange of information between Member States and the Commission. It also reminds Member States of their obligation to adopt necessary and proportionate measures to ensure the free movement of goods and to inform the Commission thereof, and it empowers the Commission to send a notification to the Member State concerned requesting that those measures be adopted within a very tight deadline <sup>(376)</sup>.

---

<sup>(373)</sup> Case C-194/94 *CIA Security* [1996] ECLI:EU:C:1996:172; Case C-443/98 *Unilever* [2000] ECLI:EU:C:2000:496.

<sup>(374)</sup> Case C-20/05 *Schwibbert* [2007] ECLI:EU:C:2007:652; Case C-390/18 *Airbnb Ireland* [2019] ECLI:EU:C:2019:1112.

<sup>(375)</sup> Council Regulation (EC) No 2679/98 of 7 December 1998 on the functioning of the internal market in relation to the free movement of goods among the Member States (OJ L 337, 12.12.1998, p. 8).

<sup>(376)</sup> For further info, see [https://ec.europa.eu/growth/single-market/barriers-to-trade/physical\\_en](https://ec.europa.eu/growth/single-market/barriers-to-trade/physical_en) and Commission Staff Working Document SWD(2019) 371 final.

## ANNEX

## TERRITORIAL APPLICATION

**Territories foreseen in Article 52(1) TEU to which Article 34 TFEU applies in line with Article 355 of the Treaty on the Functioning of the European Union:**

*The territory of the 27 EU Member States including:*

**Åland Islands** (autonomous province of Finland).

Legal Basis: Article 355(4) TFEU (ex-Article 299(5) EC).

**Azores Islands** (autonomous region of Portugal). Consisting of São Miguel, Pico, Terceira, São Jorge, Faial, Flores, Santa Maria, Graciosa, Corvo.

Legal Basis: Article 355(1) TFEU (ex-Article 299(2) EC).

**Canary Islands** (autonomous community of Spain). Comprising Tenerife, Fuerteventura, Gran Canaria, Lanzarote, La Palma, La Gomera, El Hierro.

Legal Basis: Article 355(1) TFEU (ex-Article 299(2) EC).

**French Guiana** (overseas region of France).

Legal Basis: Article 355(1) TFEU (ex-Article 299(2) EC).

**Guadeloupe** (overseas region of France).

Legal Basis: Article 355(1) TFEU (ex-Article 299(2) EC).

**Madeira** (autonomous region of Portugal). Composed of Madeira, Porto Santo, Desertas Islands, Savage Islands.

Legal Basis: Article 355(1) TFEU (ex-Article 299(2) EC).

**Martinique** (overseas region of France).

Legal Basis: Article 355(1) TFEU (ex-Article 299(2) EC).

**Mayotte** (overseas region of France).

Legal Basis: Article 355(1) TFEU.

**Réunion** (overseas region of France).

Legal Basis: Article 355(1) TFEU (ex-Article 299(2) EC).

**Saint-Martin** (Overseas collectivity of France)

Legal Basis: Article 355(1) TFEU.

*Territories linked to EU Member States to which Article 34 TFEU does not apply:*

**Aruba** (Constituent Country of the Netherlands).

Legal Basis: Article 355(2) TFEU (ex-Article 299(3) EC).

**Ceuta and Melilla** (Autonomous Cities under Spanish Sovereignty).

Legal Basis: Due to the wording of Articles 24 and 25 of the Act of Accession of Spain to the EU <sup>(1)</sup> although Article 34 TFEU probably applies to goods entering these territories from the rest of the EU, they do not seem to apply to goods originating in Ceuta and Melilla entering the rest of the EU. Therefore it does not appear that Article 34 TFEU extends to goods originating in Ceuta and Melilla.

<sup>(1)</sup> OJ L 302, 15.11.1985, p. 23.

**Faeroe Islands** (autonomous province of Denmark).

Although Denmark is responsible for the external relations of the 18 islands forming this territory, it retains a high degree of self-governance and the TFEU expressly states that these islands fall outside the scope of its territorial application.

Legal Basis: Article 355(5) (a) TFEU (ex-Article 299(6)(a) EC).

**French Polynesia** (Overseas Collectivity of France).

Legal Basis: Article 355(2) TFEU (ex-Article 299(3) EC).

**French Southern and Antarctic Territories** (Overseas Territory of France).

Legal Basis: Article 355(2) TFEU (ex-Article 299(3) EC).

**Netherlands Antilles** (Constituent Country of the Netherlands). Consisting of Bonaire, Curaçao, Saba, Sint Eustatius and Sint Maarten.

Legal Basis: Article 355(2) TFEU (ex-Article 299(3) EC).

**New Caledonia and its Dependencies** (*A sui generis* collectivity of France). Including a main island (*Grande Terre*), the Loyalty Islands and several smaller islands.

Legal Basis: Article 355(2) TFEU (ex-Article 299(3) EC).

**Saint Pierre and Miquelon** (Overseas Collectivity of France).

Legal Basis: Article 355(2) TFEU (ex-Article 299(3) EC).

**Saint Barthélemy** (French overseas collectivity)

Legal basis: Article 355(2) TFEU.

**Wallis and Futuna Islands** (French Overseas Collectivity).

Legal Basis: Article 355(2) TFEU (ex-Article 299(3) EC).

Finally, member countries of the European Economic Area (EEA), Iceland, Liechtenstein and Norway, benefit from the free movement of goods in the EU under the European Economic Area (EEA) Agreement.

---



ISSN 1977-091X (electronic edition)  
ISSN 1725-2423 (paper edition)



Publications Office  
of the European Union  
L-2985 Luxembourg  
LUXEMBOURG

**EN**