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JUSTIFICATION OF RESTRICTIONS ON IMPORTS OR EXPORTS OF GOODS ON THE GROUND OF THE PROTECTION OF HEALTH AND LIFE OF HUMANS, ANIMALS OR PLANTS

Master thesis

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Abbreviations

CJEU	– The Court of Justice of European Union
TEU	– Treaty on European Union
TFEU	– Treaty on the functioning of European Union
Mercosur	– Southern Common Market between Argentina, Brazil, Paraguay, Uruguay, and Venezuela
MS	– Member State
MSs	– Member States
TEEC	– Treaty establishing European Economic Community
WTO	– World Trade Organization

Introduction

The relevance of thesis presented. The Single Market of European Union is built on four freedoms, i.e. free movement of goods, services, persons and capital, and thus comprises an area without internal frontiers where these four freedoms are secured. The presented Master thesis is focused on free movement of goods only and its restrictions on imports or exports of goods. This Single Market prohibits customs duties on imports and exports, charges having equivalent effect, quantitative restrictions on imports and exports and all measures having equivalent effect. Custom duties and charges having equivalent effect are prohibited *ipso iure* and no justifications are acceptable. On the other hand, quantitative restrictions on imports and exports and all measures having equivalent effect are prohibited but might be justified under strict conditions and on the grounds which are laid down in the art.36 of TFEU.

Even nowadays the CJEU has to deal with various quantitative restrictions or measures having equivalent effect imposed by MSs which are hindering the trade between MSs of the European Union. The numbers of such measures limiting free movement of goods have been decreasing during the development of the European Union but there are still pending cases where the justification of restrictions on imports or exports of goods on the ground of the protection of health and life of humans, animals or plants is the main question. Thus, the CJEU serves as a protector securing free movement of goods while keeping the health and life of humans, animals and plants protected.

The process of bringing cases regarding the art.36 of TFEU to the CJEU is ongoing and therefore precise demonstration of comprehensive approach of the CJEU towards the protection of health and life is duly desired due to enormous exchange of goods and its possible danger to public health. *"There are persisting questions about the type of practice that is subject to control in the name of protecting the free movement of goods and the extent to which trade-restrictive practices may be justified."*[1] The developing case law of the CJEU in correlation with harmonizing rules provides a better understanding of the topic itself.

The object of this paper is justification of restrictions on imports or exports of goods on the ground of the protection of health and life of humans, animals or plants pursuant to art.36 of TFEU. Protection of the environment as a mandatory requirement is part of the object of this paper due to immanent interrelation with the protection of health and life. This paper does not cover other justifications determined in art.36 of TFEU, nor other mandatory requirements.

[1] Weatherill S., Free movement of goods, International and Comparative Law Quarterly, 61, pp 541550 doi:10.1017/S0020589312000048, 2012, page 541

The subject of this paper is primary and secondary law of the European Union including the jurisdiction of the CJEU providing the reader with the uniform interpretation of the object of the thesis.

The aim of this thesis is to investigate, examine and analyze the overall jurisdiction of the CJEU in correlation with primary and secondary law in order to fully comprehend its approach towards justification of measures hindering the trade between MSs. It is very important to examine the jurisdiction of the CJEU as it is the most important legal source helping lawyers, economists, scholars or laymen to fully understand when a quantitative restriction or a measure having equivalent effect to quantitative restrictions may escape prohibition and be subsequently justified. Therefore, this paper is aiming to provide an explicit explanation of the topic, so that its reader would afterwards be able to correctly anticipate the outcome of a case, i.e. whether a disputable measure is justifiable or not. Only the most relevant and widely known cases are chosen in order to fulfill this objective.

The ***thesis*** focuses on four main premises. First of all, it aims to show that a disputable measure can be justified only after having met strict requirements interpreted in the case law of the CJEU. Secondly, it demonstrates that a MS is successful in justifying a measure only having proved that the measure is absolutely necessary to attain the protection of health and life of humans, animals and plants, and does not aim at protecting its domestic market. According to the third premise, the prohibition on use is a strong trade barrier under prohibition of art.34 of TFEU hindering the access of products into a MS. Finally, the paper aims to defend a need to include the protection of the environment into the art.36 of TFEU in order to diminish the confusion between application of mandatory requirements and art.36 of TFEU.

Methodology. In order to achieve aforementioned aims and tasks, this paper first of all provides a thorough explanation of free movement of goods and quantitative restrictions on imports and exports, all measures having equivalent effect, mandatory requirements, and concept of goods. Subsequently, detailed examination and analysis of the case law of the CJEU constitutes the main part of the thesis. The most relevant cases are demonstrated in order to provide the reader with the proper interpretation of art.36 of TFEU. All cases are classified according to the matter of facts into several subdivisions. Thus, the jurisdiction of the CJEU and the comments of the author serve as a comprehensive source explaining the object of this paper.

Structure. The thesis is divided into several parts, namely, introduction, three substantial parts, each of which is divided into smaller ones, bibliography, and the summary. The first and the second parts of the thesis present analysis of free movement of goods and the concept of

goods within the European Union law. The last, essential part of the thesis presented discusses the justification on the ground of the protection of health and life of humans, animals or plants. This part is subdivided into more than ten subdivisions reflecting the nature of restrictions, applicable principles or other related issues. Some of the abovementioned subdivisions are again subdivided in order to focus on specific products or restrictions.

Free movement of goods

Custom duties on imports and exports, charges having equivalent effect and quantitative restrictions on imports and exports and all measures having equivalent effect

The European Union is an organization *sui generis* gathering attributes of international organization, confederation and federation into one unique entity on the international level with the aim of economic and politic integration where four freedoms are secured – the free movement of goods, persons, services and capital. These four freedoms are immanent and integral part of the Internal Market, or so-called Single Market, and its legal background is set forth in the Lisbon Treaty, more specifically in the art.26 of the TFEU which stipulates: *"The Internal Market shall comprise an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured in accordance with the provisions of the Treaties."* Thus, the essence of Internal Market is embedded in the primary law and is the main core of functioning of the European Union and its long-lasting integration.

European Union, creating the highest form of economic integration with its Internal Market and as an Economic and Monetary Union with its common currency, constitutes a unique entity with well-secured free movement of goods. Therefore, the European Union might be labeled as a Single Market as there is no other organization comparable to this form of integration in the entire world.[2]

Art. 28 of TFEU provides clear definition of customs union as a prerequisite for proper functioning of the free movements of goods as following*:"The Union shall comprise a customs union which shall cover all trade in goods and which shall involve the prohibition between Member States of customs duties on imports and exports and of all charges having equivalent effect, and the adoption of a common customs tariff in their relations with third countries"*. Hereby the free movement of goods possesses two elements – internal and external. Internal part of customs union prohibits any customs duties and charges having equivalent effect between MSs and guarantees undisturbed trade between them. Adoption of common external tariffs is an external element which enables equal levying of products on external borders of the European Union and herewith overcomes the concept of a free trade area and its disadvantages regarding various external tariffs in different MSs.

[2] Mercosur might become an entity very similar to European Union

In order to preserve well-functioning of free movement of goods, attention must be paid to three main areas:

1. Custom duties on imports and exports and charges having equivalent effect;
2. Quantitative restrictions on imports and all measures having equivalent effect / Quantitative restrictions on exports and all measures having equivalent effect;
3. Discriminative internal taxations.

All these areas shall be prohibited pursuant to the TFEU. Custom duties on imports and exports and charges having equivalent effect are prohibited according to the art.30 of TFEU and there are no justifications allowed, unlike the quantitative restrictions and measures having equivalent effect. Custom duties and charges having equivalent effect are detected due to their feature of a custom paid on the frontier of the MSs. The CJEU held: *"Whatever its designation and mode of application, a pecuniary charge which is imposed unilaterally on goods imported from another MS when they cross a frontier constitutes a charge having an effect equivalent to a customs duty."*[3] They are paid due to crossing of a frontier of another MS while internal taxes, which are not prohibited unless they are discriminatory, are levied after crossing a border. Quantitative restrictions on imports and all measures having equivalent effect are more frequently applied because custom duties and charges having equivalent effect are easier to be detected.

Quantitative restrictions on imports and all measures having equivalent effect and quantitative restrictions on exports and all measures having equivalent effect shall be prohibited as referred in art.34 and art.35 of TFEU. There is a clear reason for embedding one concept into two articles and thus differentiating between export and import regarding these restrictions. Art.34 of TFEU applies to discriminatory and to indistinctly applicable measures where art.35 of TFEU only to discriminatory measures.[4] There is no legal definition of these restrictions and measures in primary law and in order to secure uniform interpretation of the European Union law, the CJEU came up with proper definitions in its jurisdiction. The CJEU defined the prohibition on quantitative restrictions very broadly in order to easily subsume acts of MSs under such a definition. It adjudicated*: „The prohibition on quantitative restrictions covers measures which amount to a total or partial restraint of, according to the circumstances, imports, exports*

[3] Case 87-75 Bresciani v. Administrazione Italiana delle Finanze [1976], para. 9

[4] Craig P., De Burca G., EU law text, cases and materials, fifth edition, Oxford University Press 2011, page 680, see approach of the CJEU in Case 15/79 P.B. Groenveld BV v Produktschap voor Vee en Vlees [1973], para. 9, National measure prohibiting all manufacturers of meat products from having in stock or processing horsemeat was found compatible with the Treaty

or goods in transit.“[5]

The CJEU defined measures having equivalent effect as*: „All trading rules enacted by member state which are capable of hindering, directly or indirectly, actually or potentially Intra-Community trade, are to be considered to as measures having an effect equivalent to quantitative restrictions.”*[6] Thus, only hindering of the trade is enough in order to find a measure in breach of art.34 and art.35 of TFEU. In the famous case *Buy Irish*[7], the CJEU found national campaign, which promoted the sale and purchase of domestic products, in contrary to article 34 of TFEU even though the Irish government emphasized that the campaign had no restrictive effect on imports since the proportion of Irish goods to all goods sold on the Irish market had fallen from 49.2% in 1977 to 43.4% in 1980. This proves that only a potential hindrance of the free movement of goods with no actual impact is enough to declare that a MS has failed to fulfill its obligations pursuant to the abovementioned articles. What must be born in mind is that the prohibition of quantitative restrictions and of all measures having equivalent effect applies not only to national measures but also to measures adopted by the Community/Union institutions.[8]

Internal discriminative taxation deals with a different situation. Goods from one MS are free to enter the market of another MS, no customs duties are paid and they are not under obligation to meet certain quantitative measures, but they nevertheless have a disadvantageous position due to internal taxation which favors domestic products. Pursuant to the art.110 of the TFEU *“any internal taxation of any kind in excess of that imposed directly or indirectly on similar products imposed directly or indirectly shall be prohibited. Simultaneously is prohibited any internal taxation of such a nature as to afford indirect protection to other products.”* Thus, every MS has the own competence to determine its internal taxes unless they are discriminatory.

Custom duties on imports and exports and charges having equivalent effect are prohibited as such and neither primary law nor jurisdiction of the CJEU provide any justifications for such acts. Situation with quantitative restrictions on imports and exports and all measures having equivalent effect is different. After having met certain requirements, a MS is able to escape unlawfulness of such a measure. Art.36 of TFEU thus provides a scale of grounds for justifying measures which quantitatively or in other way restrict trade between MSs.

“The provisions of Articles 34 and 35 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of

[5] Case 2-73 Riseria Luigi Geddo v Ente Nazionale Risi [1973], para. 7
[6] Case 8-74 Procureur du Roi v Benoît and Gustave Dassonville [1974], para. 5
[7] Case 249/81Commission of the European Communities v Ireland. [1981], para. 22-30
[8] Case C-51/93 Meyhui NV v Schott Zwiesel Glaswerke AG [1994], para. 11

- *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."*

This article applies to discriminatory/distinctly applicable measures imposed by a MS which distinguish between domestic products and products stemming from other MSs. Therefore, any discriminatory/distinctly applicable measure falling under the art.34 or art.35 might draw back from the prohibition if it is based on one of the aforementioned grounds and does not constitute a means of arbitrary discrimination or a disguised restriction on trade between MSs. This wording comes from Article XX: General Exceptions of GATT from 1947[9], which allows WTO MSs to deviate from their obligations under GATT in order to pursue public interests such as protection of health and life of humans, animals and plants.[10] Art. 36 of TFEU was not substantially amended since 1957, even though there might be a need to add some new upcoming grounds for justifications.

Mandatory requirements

The CJEU came up with the doctrine of mandatory requirements in order to widen the grounds for justifications apart from the art.36 of TFEU and which applies to indistinctly applicable measures. The CJEU in *Cassis de Dijon*[11] case thus created new justifications for the measures that are applied indistinctly to all products but have discriminative impact on imported goods. The CJEU held*:"Those provisions may be recognized as being necessary in order to satisfy mandatory requirements relating in particular to the effectiveness of*

- *fiscal supervision,*
- *the protection of public health,*
- *the fairness of commercial transaction and*
- *the defense of the consumer."*[12]

National provisions in the aforementioned case fixing a minimum alcohol content of alcoholic beverages which applied to domestic and imported goods equally fell under the

[9] http://www.wto.org/english/docs_e/legal_e/gatt47_02_e.htm
[10] Diebold N.F., Standards of nondiscrimination in international economic law, International and Comparative Law Quarterly, 60, pp 831865 doi:10.1017/S0020589311000418, 2011, page 850
[11] Case 120/78 Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein [1979], para.8
[12] Ibidem

prohibition because of negative impact on imported goods. The principle of mutual recognition, sometimes called mandatory requirements test by some scholars[13], was established in this case and determines that a product legally produced and marketed in one MS shall have an access to and be marketed in another MS in absence of common rules at European Union level.

In order to justify quantitative restrictions on imports and exports and all measures having equivalent effect, two main different ways might be used according to the character of the measure, i.e. if it is distinctly or indistinctly applicable. Article 36 of TFEU is exhaustive and the CJEU shall not use any other grounds for distinctly applicable measures limiting trade between MSs. Simultaneously, mandatory requirements shall be applied to indistinctly applicable measures. However, there is no strict rule, which could be uniformly applied, stating that mandatory requirements cannot be used as grounds of justifications for distinctly applicable measures.[14]

Moreover, the CJEU emphasized that: *"Article 36 of the Treaty must be strictly interpreted and the exceptions which it lists may not be extended to cases other that those which have been exhaustively laid down, article 36 refers to matters of a non-economic nature."*[15] For instance, a measure which restricts intra-Union trade cannot be justified by a MS's wish to secure the survival of an undertaking.[16]

This article shall not justify disputable measures based on fairness of commercial transactions, economic policy or the protection of creativity and cultural diversity because they are not embedded in the art.36 of TFEU.[17] On the other hand, the list of mandatory requirements is not exhaustive and the CJEU comes up with other new grounds for such justifications, for instance:

- maintaining of press diversity[18],
- protection of younger persons[19] or even
- road safety[20].

[13] For instance: Jacobs F., The role of the European Court of Justice in the Protection of environment, Journal of Environmental Law (2006) Vol 18 No 2, 185–205, doi: 10.1093/jel/eql012. Advance Access publication 5 May 2006, page. 188

[14] Vėgėlė I., Europos Sąjungos teisė, Vidaus rinkos laisvės, konkurencija ir teisės derinimas, Valstybes įmone registrų centras, Vilnius 2011, page 99-100

[15] Case 95/81 Commission of the European Communities v Italian Republic. [1988], para. 27

[16] Case C-324/93 The Queen v Secretary of State for Home Department, ex parte Evans Medical Ltd and Macfarlan Smith Ltd [1995], para.36

[17] Arnull A.M, Dashwood A.A, Ross M.G & Wyatt, European Union law fourth edition, London Sweet & Maxwell 2000, page 345-346

[18] Case C-368/95 Vereinigte Familiapress Zeitungsverlags- und vertriebs GmbH v Heinrich Bauer Verlag. - Reference for a preliminary ruling [1997], para. 18

[19] Case C-170/04 Rosengren and Others v Riksåklagaren [2007], para. 50-51 & 58

[20] Case C-110/05 Commission of the European Communities v Italian Republic [2005], para. 60-64

Protection of the environment became the most important mandatory requirement as the CJEU held: *"protection of the environment constitutes one of the Community's essential objectives, it is such a requirement"*[21] and pointed out that the principle of freedom of trade is not to be viewed in absolute terms but is subject to certain limits justified by the objectives of general interest and confirms that the environmental protection is one of the Community's essential objectives.[22] The list of mandatory requirements might be broadened during the following decades.

Definitions of goods according to the Jurisdiction of the CJEU

Concept

Concept of goods is not defined in the primary law of the European Union. Therefore, the CJEU, in its well-settled case law, came up with a proper definition. The most significant case was 7/68 Commission vs. Italy where Italy failed to fulfill its obligations under the Treaty by levying a tax on the exportation of articles possessing artistic or historic value. The primary question was whether these goods may be classified as goods pursuant to the European Union law. The CJEU provided us with the main definition of goods, as follows: *"By goods, within the meaning of article 9 of the EEC 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."*[23] In order to use articles regarding free movement of goods, the disputable measures restricting trade must apply to items with determinable value and must be able to form a subject of a commercial transaction.

Examples

Notion of goods was clarified in a huge amount of cases. For instance, the CJEU held: *„sound recordings, even incorporating protected musical works, are products to which the system of the free movement of goods provided for the treaty applies"*[24]. Even waste was acknowledged as 'goods' in *Belgium waste case* where the CJEU held: "*objects which are shipped across a frontier for the purposes of commercial transactions fall within the scope of*

[21] Case 302/86 Commission of the European Communities v Kingdom of Denmark [1988], para. 1 in Summary
[22] Case 240/83 Procureur de la République v Association de défense des brûleurs d'huiles usagées (ADBHU) [1985], para. 1 in Summary
[23] Case 7-68 Commission of the European Communities v Italian Republic [1968], para. 2 in Summary
[24] Case 55/80 and 57/80 Musik-Vertrieb membran GmbH et K-tel International v GEMA [1981], para. 8

Article 30 of the Treaty, whatever the nature of those transactions, with the result that waste, whether recyclable or not, is to be regarded as goods."[25]

It is sometimes difficult to distinguish between goods and services, and which provisions of the Treaty apply but the CJEU is carefully splitting the subject matter in a dispute between goods and services, for instance: *"The transmission of television signals, including those in the nature of advertisements, comes, as such within the rules of the Treaty relating to services but trade in articles, sound recordings, films, apparatus and other products used for the diffusion of television signals is subject to the rules relating to freedom of movement for goods."*[26] In another case the CJEU was considering the possibility of means of payment to be understood as goods falling within the terms of the Treaty. Means of payment, as such, are not to be considered as goods unless they are silver alloy coins which are legal tender in a MS or gold coins such as "*krugerrands*" which are produced in a non-member state but which circulate freely within a MS.[27] Even electricity is understood as goods, as indicated in the most relevant case 6/64 *Costa* where the main features of the European Union law were defined. In this case electricity was considered as goods in transit.

Living animals are also goods. The most widely known case dealing with the prohibition of keeping any species of bee, other than the subspecies *Apis mellifera,* on an island is such an example (Læsø brown bee).[28] Freshwater crayfish[29], live sheep[30] or such biological materials as semen are goods as well.[31] Medical products[32] or narcotic drugs (diamorphine) for pharmaceutical or medical purposes[33] are considered as goods where the free movement of these products has to be ensured.

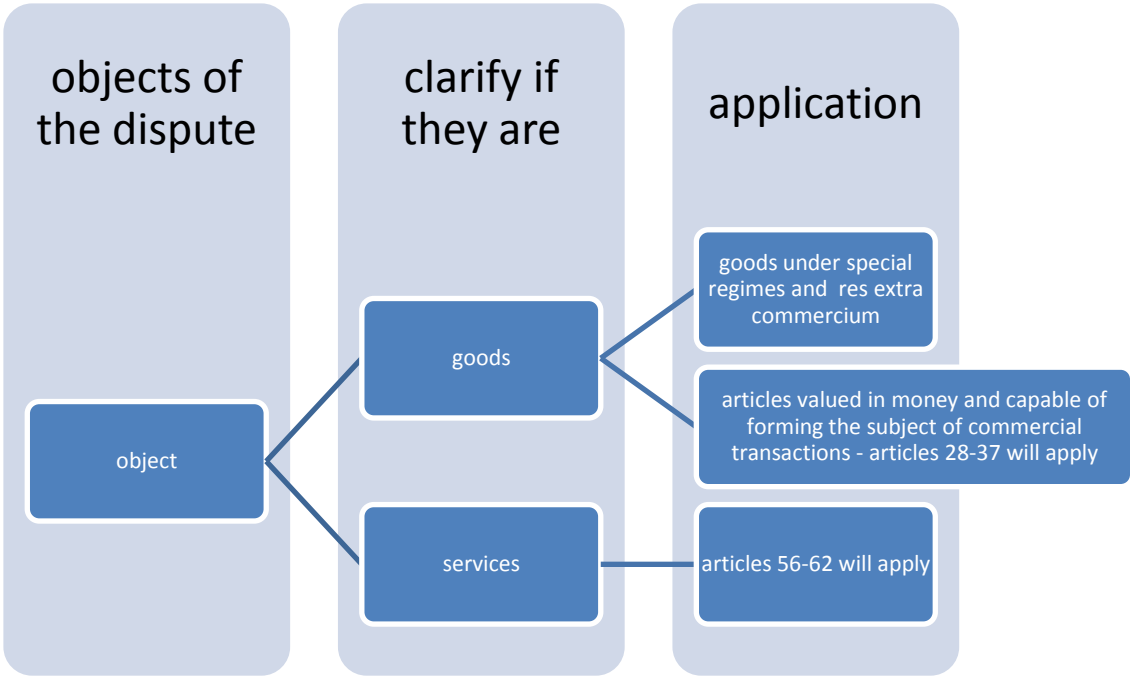
Weapons are not classified as goods because they possess special legal regime. The art.346 TFEU and following stipulate that the provisions of the treaties shall not preclude the application of the following rule – *"any Member State may take such measures as it considers necessary for the protection of the essential interests of its security which are connected with the production or trade in arms, munitions and war material."* Also products under application of

[25] Case C-2/90 Commission of the European Communities v Kingdom of Belgium [1992], para. 26-28
[26] Case 155-73 Giuseppe Sacchi. - Reference for a preliminary ruling: Tribunale civile e penale di Biella – Italy [1974], para. 3 in Summary
[27] Case 7/78 Regina v Ernest George Thompson, Brian Albert Johnson and Colin Alex Norman Woodiwiss [1978], para. 1-2 in Operative part
[28] Case C-67/97 Reference for a preliminary ruling: Kriminalretten i Frederikshavn – Denmark [1998], para. 38
[29] Case C-131/93 Commission of the European Communities v Federal Republic of Germany [1978], para. 25
[30] Case C-5/94 The Queen v Ministry of Agriculture, Fisheries and Food, ex parte: Hedley Lomas (Ireland) Ltd [1996], para. 13
[31] Case C-323/93 Société Civile Agricole du Centre d'Insémination de la Crespelle v Coopérative d'Elevage et d'Insémination Artificielle du Département de la Mayenne [1994] & Case C-235/91 Commission of the European Commission v Ireland [1992], para. 40
[32] Case C-212/03 Commission of the European Communities v French Republic [2005], para. 49
[33] Case C-324/93 The Queen v Secretary of State for Home Department, ex parte Evans Medical Ltd and Macfarlan Smith Ltd [1995], para. 1 in Operative part

the Treaty establishing the European Atomic Energy Community possess such a special regime.[34] Articles that are excluded from the conception of goods are *res extra commercium*, like drugs, human organs or chewing tobacco.[35]

Definition

Goods must, therefore, meet certain requirements in order to have the articles relating to the free movement of goods applicable. Next steps should be followed:



Firstly, the clear distinction between goods and services must be determined. Afterwards, it must be indicated that they do not fall under special regimes or group of *res extra commercium* and if they comply with the definition involved in the case 7/68 Commission vs. Italy.

Therefore, goods pursuant to the case law of the CJEU, might be defined as products, tangible or intangible, which can be valued in money and be capable, as such, of forming the subject of commercial transactions and do not fall neither under special regime, nor *res extra commercium* or other provision regarding the free movement of services and capital. Only such products are understood as goods from the point of view of the European Union law, thus articles regarding the free movement of goods will apply.

[34] Karas V., Kralik A., Európske právo, druhé doplnené a prepracované vydanie, Iura Edition, page 255
[35] Svoboda P., Úvod do evropského práva, 3.vydaní 2010, beckove mezioborové učebnice, page 174.

Justification on the grounds of protection of health and life of humans, animals or plants

The free movement of goods is one of four freedoms of the European Union, an essential pillar of its functioning and the leading reason for the European integration. The free movement of goods must be secured, protected and guaranteed. The unlimited free movement of goods is not beneficial and might harm values of MSs and the European Union itself. Thus, MSs of the European Union adopt quantitative restrictions and measures having equivalent effect in order to protect certain values – public morality, public policy, public security, health and others as listed in the art.36 of TFEU. Basically, quantitative restrictions or measures having equivalent effect are prohibited by the TFEU but may escape the prohibition if they are imposed in the compliance with the art.36 of TFEU.

The protection of health and life of humans, animals or plants is thus the only one option for justifying quantitative restrictions or measures having equivalent effect. Protection of health is a necessity and the TFEU sets forth: *"A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities."*[36] Therefore, the protection of human life must be properly involved in all activities of the European Union and this provision works as a *lex generalis*. The art.36 of TFEU deals specifically with the protection of health in correlation with the free movement of goods only.

Subsequently, it is up to the discretion of the CJEU to consider whether the aim of such a restriction is the protection of health and life or the ostensible hidden purpose to protect national market and whether such a restriction could have been achieved by a less restrictive measure. MSs are obliged to prove that the merits of facts follow under the art.36 of TFEU and no intentional discrimination occurs.

Quantitative restrictions or measures having equivalent effect relating to the protection of health and life of humans, animals or plants exist in various forms as restrictions, tests, total bans, issuing of licenses or requiring excessive information and can be derogated by the art.36 of TFEU when such measures are distinctly applicable. Protection of health is as well included in mandatory requirements stemming from the *Cassis de Dijon* case and applies to indistinctly applicable measure. It does not matter if such a restrictive measure is imposed distinctly or indistinctly on goods because protection of public health might be used in both ways - i.e. through the art.36 of TFEU or as a mandatory requirement of *Cassis de Dijon*.

All the grounds mentioned in the art.36 of TFEU have the same legal value but the CJEU

[36] Art.168 of TFEU, art.35 of Charter of Fundamental Rights of the European Union

considers the protection of health and life as a superior one when stipulating: *"it should be borne in mind that the health and life of humans rank foremost among the property or interests protected by Article 36 of the Treaty."*[37] Hereby, the protection of health and life can be regarded as the most important one.

What must be pointed out is that national authorities have to demonstrate in every particular case that their rules are necessary to give effective protection to the interests referred to the art.36 of TFEU and *"to show that the marketing of the product in question creates a serious risk to public health."*[38] Therefore, national authorities face the burden of proof.

Proportionality

It is a general principle of the European Union embedded in art.5 (4) of TEU: *"Under the principle of proportionality, the content and form of Union action shall not exceed what is necessary to achieve the objectives of the Treaties. The institutions of the Union shall apply the principle of proportionality as laid down in the Protocol on the application of the principles of subsidiarity and proportionality."* All the principles, as principle of loyalty, conferral, subsidiarity and proportionality, belong to the leading principles of the functioning of the European Union. In other words, the principle of proportionality prevents the European Union from adopting actions beyond what is necessary for achieving certain objectives. The very same principle applies to MSs in order to successfully apply art.36 of TFEU and to justify disputable measures. The CJEU does not justify a measure if a desired goal could have been achieved by a less restrictive measure. Moreover, art.36 of TFEU sets forth: *„Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States."* This article permits to derogate from the doctrine of the free movement of goods only to the extent to which such derogation is to be justified for the attainment of the objective laid down in the art.36 of TFEU.[39] The general approach of the CJEU is that only those measures which are necessary to attain a desired objective are justified.[40] What must be pointed out is that arbitrary discrimination, disguised restriction on trade and the principle of proportionality should not be considered in isolation.[41] They must be evaluated together because one measure might be breaching the principle of proportionality and simultaneously causing disguised restriction on trade and creating discrimination. For that reason

[37] Case C-473/98 Kemikalieinspektionen v Toolex Alpha AB [2000], para. 38
[38] Case 227/82 Criminal proceedings against Leendert van Bennekom [1983], para. 6
[39] Case 5-77 Carlo Tedeschi v Denkavit Commerciale s.r.l. [1997], para. 34
[40] Case 251/78 Firma Denkavit Futtermittel GmbH v Minister für Ernähung, Landwirtschaft und Forsten des Landes Nordrhein-Westfalen Reference for a preliminary ruling: Verwaltungsgericht Münster – Germany [1979], para. 28
[41] Arnull A.M, Dashwood A.A, Ross M.G & Wyatt, European Union law fourth edition, London Sweet & Maxwell 2000, page 350

strict distinction between abovementioned classifications would seem rather counter-productive. Last but not least, the principle of proportionality must be met even in the absence of harmonization. However, if a MS can demonstrate that adopting of an alternative measure would have a detrimental effect on other legitimate interests (as e.g. fundamental rights), this has to be taken into consideration in the assessment of proportionality.[42]

Principle of proportionality has been a decisive element in multiple cases. In *German purity beer* case[43] Federal Republic of Germany prohibited marketing of beers lawfully manufactured and marketed in another MS if they did not comply with *Biersteuergesetz*. *Biersteuergesetz* puts down conditions regarding utilization of the designation "*Bier".* Thus, a producer was allowed to use this designation if he produced fermented beverages only from malted barley, hops, yeast and water. Moreover, foodstuff law prohibited utilization of unauthorized additives, whether pure or mixed with other substances for the manufacture of processing. The foodstuff law, in conjunction with *Biersteuergesetz*, had the effect of prohibiting the importation of beers containing substances covered by the ban on the use of additives into Germany. These *"purity requirements"* were designed to protect public health and designation *"Bier"* to protect consumers, as Germany argued. By applying rules of designation of *Biersteuergesetz,* Germany failed to fulfill its obligations under the TFEU due to non-compliance with the principle of proportionality. The CJEU held*: "... may be ensured by means which do not prevent the importation of products which have been lawfully manufactured and marketed in other MS and, in particular, by the compulsory affixing of suitable labels giving the nature of the product sold."*[44] Relating to prohibition of additives, the CJEU expressed that additives do not present a risk to public health and meet a real need, especially a technical one. This total ban on all additives for beers was in clear breach of the principle of proportionality and was therefore not covered by the art.36 of TFEU. A reasonable question might arise, whether such a measure was not aiming at the protection of domestic production of beer only.

The evaluation of the principle of proportionality is the most important element in the process of deciding whether a measure should or should not be justified. The CJEU does not justify a disputable measure if the desired objective could have been achieved by a less restrictive measure. If such a measure goes beyond what was necessary for the achievement of the protection of health and life, the CJEU declares that MS has failed to fulfill its obligations pursuant to the Treaty.

[42] http://ec.europa.eu/enterprise/policies/single-market-goods/files/goods/docs/art34-36/new_guide_en.pdf page 30
[43] Case 178/84 Commission of the European Communities v Federal Republic of Germany [1994] para. 1-37
[44] Ibidem para. 35

Protection of health and life of humans

This part is dedicated to the demonstration of certain products, substances or additives that have direct effect on human health and to the presentation of the approach of the CJEU to their usage, consequences and justifications.

Medical Products and their sale

Medical products are very often the subjects of legal disputes due to their direct effect on human health. The CJEU defined medical products as *"products whose pharmacological properties have been scientifically observed and which are genuinely designed to make a medical diagnosis or to restore, correct or modify physiological functions"*[45] and had to deal with the prohibition of sale of the products which were subject to medical prescription, by mail order.[46] Such a total ban on medical products which are subject to medical prescription cannot be assumed as a selling arrangement stemming from *Keck and Mithouard*[47] case because such a ban affects more negatively producers from other MSs due to impediment of the access of their products to the market.[48] Internet sale is the main significant way of sale for foreign producers but domestic producers are still able to use their dispensaries. Therefore, such a national act, prohibiting the sale by mail order of medical products which may be sold only in pharmacies and are subject to medical prescription, is a measure having equivalent effect to a quantitative restriction but it is justified on the ground of protection of health and life of humans. The CJEU held that the aforementioned disputable measure is about to *"ensure that the medicine is handed over either to the customer himself, or to a person to whom its collection has been entrusted by the customer"*.[49] An absolute prohibition on the sale of all medical products by mail order, regardless of being subject to a medical prescription, would go beyond what is necessary to achieve the legitimate objective, i.e. the protection of human health and thus cannot not rely on justification embedded in art.36 of TFEU.

Even Hungarian Government was not able to justify its national legislation authorizing the sale of contact lenses only in shops which are specialized in the sale of medical devices and prohibiting the sale of contact lenses via Internet. Such legislation was held disproportionate to the objective of ensuring the protection of public health as it could have been ensured by measures less restrictive than the abovementioned (e.g. supplementary information and advice to

[45] Case C-319/05 Commission of the European Communities v Federal Republic of Germany [2005], para 61
[46] Case C-322/01 Deutscher Apothekerverband eV v 0800 DocMorris NV and Jacques Waterval [1983] para. 24
[47] Joined cases C-267/91 and C-268/91 criminal proceedings against Bernard Keck and Daniel Mithouard[1993]
[48] See also Case C-239/02 Douwe Egberts NV v Westrom Pharma NV and Others [1983] "Absolute prohibition of advertising the characteristics of a product is liable to impede access to the market by products from other Member States more than it impedes access by domestic products, with which consumers are more familiar".
[49] Ibidem, para. 119

the customer by means of the interactive features to be found on the supplier's Internet site).[50] The CJEU already held: *"Treaty must be interpreted as precluding national legislation which reserves the sale of optical appliances and corrective lenses solely to holders of an optician's certificate."*[51] Moreover, the Federal republic of Germany failed to fulfill its obligations under the Treaty when enacted a law laying down that a contract for the supply of medicinal products is subject to cumulative conditions whose effect is to make it impossible in practice for a domestic hospital to be supplied on a regular basis by pharmacies established in other Member States.[52] Furthermore, imposing prior authorization procedure to personal imports of homeopathic medicinal products was also found incompatible with the Treaty.[53]

The necessity to ensure that a MS has reliable medical supplies for essential medical purposes may justify a barrier to the trade between MSs if such a measure is aimed at protection of health and life of humans. Therefore, refusing licenses for importation of drugs from another MS may be successfully justified if it is not based on the need to safeguard an undertaking's survival and that the protection of health and life of humans cannot be achieved by less restrictive measures.[54]

A monopoly for dispensing pharmacists, possessing exclusive rights to sell medicinal and para-pharmaceutical[55] products, is able to affect the possibilities of marketing imported products and may accordingly constitute a measure having an effect equivalent to a quantitative restriction. However, such a monopoly may be justified on the ground of the protection of health and life of humans.[56] The CJEU held: *"some form of monopoly on the retail sale of such products is granted to pharmacists by reason of the safeguards which pharmacists must provide and the information which they must be in a position to furnish to the consumer"* and *"their monopoly over those products may be presumed to constitute an appropriate way of protecting public health."*[57] Thus, the interest of medical products being sold by qualified staff is obvious and the protection of health and life of humans and customers must be secured. The CJEU held that it is for the national court to determine whether such a monopoly is necessary and whether

[50] Case C-108/09 Ker-Optika bt v ÀNTSZ Dél-dunántúli Regionális Intézete [2010], para 59-78
[51] Case C-271/92 Laboratoire de Prothèses Oculaires v Union Nationale des Syndicats d'Opticiens de France and Groupement d'Opticiens Lunetiers Détaillants and Syndicat des Opticiens Français Indépendants and Syndicat National des Adapteurs d'Optique de Contact [1993], para. 1 in Operative part
[52] Case C-141/07 Commission of the European Communities v Federal Republic of Germany [2008], para. 1
[53] Case C-212/03 Commission of the European Communities v French Republic [2005], para. 49
[54] Case C-324/93 The Queen v Secretary of State for Home Department, ex parte Evans Medical Ltd and Macfarlan Smith Ltd [1995], para. 36
[55] Products relating directly or indirectly to health care as toiletries and cosmetics, dietary products, and special foods (baby foods and vitamins). *See* 90/33/EEC: Commission Decision of 14 December 1989 relating to a proceeding under Article 85 of the EEC Treaty (IV/32.202-APB)
[56] Case C-369/88 Criminal proceedings against Jean-Marie Delattre, Reference for a preliminary ruling: Tribunal de grande instance de Nice – France [1991], para. 52
[57] Ibidem

the protection of public health cannot be achieved by less restrictive measures.

Such measures will be justified only if the purpose of protection of health and life of human beings is apparent and if they meet the principle of proportionality. The CJEU is aware of possible danger of improper or false usage of medicinal or para-pharmaceutical products but quantitative restrictions or measures having equivalent effect cannot go beyond what is necessary to protection of the public health.

Pesticides

Pesticides might be divided into plant-protection products[58], defined in Regulation (EC) No 1107/2009, or biocidal products[59], defined in Directive 98/8/EC of the European Parliament and of the Council. The CJEU was obliged to interpret art.36 of TFEU relating to the protection of humans and animals with regards to plant-protection products. In the case *Nijman*[60], the CJEU had to the deal with a national law prohibiting the sale, placing in stock or store or use of any plant-protection product which had not been authorized by *Bestrijdingsmiddelenwet* decree of the Netherlands and therefore had to review its compliance with the Treaty. The CJEU in this case emphasized: *"plant-protection products present significant risks to the health of humans and animals and to the environment"*[61] and therefore leaves it to the MSs in the absence of full harmonization to decide *"at what level they wish to set the protection of the life and health of humans"*[62]. Therefore, the Netherlands was able to impose penalty for utilization, sale and stocking of plant-protection products which were not authorized by domestic legislation.

In the case *Albert Heijn BV*[63] criminal proceedings were brought against Albert Heijn BV for having in stock a quantity of apples, intended for human consumption, having potential danger to public health due to presence of 1.0 milligram of the pesticide. Apples were imported from Italy where they had been legally placed on the market. The CJEU held: *"pesticides constitute a major risk to human and animal health and to the environment…, do not have only a*

[58] Products consisting of or containing active substances, safeners or synergists, and intended for: (a) protecting plants or plant products against all harmful organisms or preventing the action of such organisms, unless the main purpose of these products is considered to be for reasons of hygiene rather than for the protection of plants or plant products; (b) influencing the life processes of plants, such as substances influencing their growth, other than as a nutrient; (c) preserving plant products, in so far as such substances or products are not subject to special Community provisions on preservatives; (d) destroying undesired plants or parts of plants, except algae unless the products are applied on soil or water to protect plants; (e) checking or preventing undesired growth of plants

[59] Active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means.

[60] Case 125/88 Criminal proceedings against H. F. M. Nijman. Reference for a preliminary ruling: Gerechtshof 's-Gravenhage – Netherlands [1989], para. 2

[61] Ibidem, para. 13

[62] Ibidem, para. 14

[63] Case 94/83 Criminal proceedings against Albert Heijn BV, Reference for a preliminary ruling: Arrondissementsrechtbank Haarlem – Netherlands [1984], para. 2

favorable effect on plant production, since they are generally toxic substances or preparation with dangerous side effects."[64] MSs are allowed to regulate the presence of pesticides on foodstuffs *"in a way which may vary from one country to another according to the climatic conditions, the normal diet of the population and their state of health"*[65] if the relevant harmonized rules do not cover such pesticides. Thus, MSs are allowed to impose a penalty in criminal law for a failure to comply with provisions prohibiting the sale, placing in stock or store, or the use of a plant-protection product in the absence of overall harmonization.[66]

The CJEU clearly demonstrated: *"legal provision of a Member State prohibiting pesticides for non-agricultural use which have not been previously authorized from being marketed, acquired, offered, put on display or sale, kept, prepared, transported, sold, disposed of for valuable consideration or free of charge, imported or used, constitutes a measure having an effect equivalent to a quantitative restriction within the meaning of Article 30 of the Treaty,"*[67] even though such pesticides for non-agricultural use are lawfully marketed in another MS. This judgment stressed out that in the absence of harmonizing rules, national legislation, prohibiting the marketing of a biocidal product containing dangerous substances without prior authorization from the competent authorities, is justified even though such product had already been authorized for sale in another Member State.

In the absence of harmonizing rules regarding the product, a MS is allowed to adopt such strict rules and mutual recognition does not apply. Therefore, a requirement asking for prior authorization can be justified but *"competent authorities are not entitled unnecessarily to require technical or chemical analyses or laboratory tests when the same analyses or tests have already been carried out in that other Member State and their results are available to those authorities or may at their request be placed at their disposal."*[68] Simultaneously, MSs operating the approval procedure must ensure that no unnecessary control expense is incurred if the control carried out in the MS of origin satisfied the requirements of the protection of public health in the importing MS.[69]

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[64] Ibidem, para. 13
[65] Case 54/85 Ministère public against Xavier Mirepoix. - Reference for a preliminary ruling: Tribunal de police de Dijon – France 1986], para. 15
[66] Case 125/88 Criminal proceedings against H. F. M. Nijman. Reference for a preliminary ruling: Gerechtshof 's-Gravenhage – Netherlands [1989], para. 19
Absence of harmonization was mitigated by Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides.
[67] Case C-293/94 proceedings against Jacqueline Brandsma. - Reference for a preliminary ruling [1996], para. 6
[68] Ibidem, para. 13
[69] Case 272/80 Criminal proceedings against Frans-Nederlandse Maatschappij voor Biologische Producten BV [1981], para. 15

Prohibited additives

The CJEU had to deal with prohibitions of certain additives in MSs which might be justified by the protection of health and life of human beings. These additives must be understood as substances not normally consumed as a food in itself and not normally used as a characteristic ingredient of food, whether or not it has nutritive value, the intentional addition of which to food for a technological purpose results in it or its by-products becoming directly or indirectly a component of such foods.[70]

The most widely known case dealing with such additives is a so-called *Nisin*[71] case. The main additive in question, not authorized by the applicable law in the Netherlands (competent minister has not authorized usage of these antibiotics), was Nisin[72], which was used by one manufacturer producing cheese for domestic sale and export. Manufacturer strongly emphasized that the quantity of nisin was not presenting any danger to the health of human beings and the usage of it was even authorized in other MSs. Thus, the question arose whether such a prohibition is compatible with the Treaty and whether it does not obstruct the free movement of goods. In other words, if a MS can decide on its own which additives present danger to public health, even though such additives may be used in other MSs. It is apparent that such a prohibition of usage of Nisin was capable of hindering trade between MSs and therefore it was found by the CJEU as a measure having equivalent effect to quantitative restrictions.

The CJEU pointed out that studies are not able to agree on the maximum quantity of Nisin which a person may consume without causing serious risk to his health and therefore held: *"in the view of the uncertainties prevailing in the various MSs regarding the maximum level of Nisin which must be prescribed in the respect of each preserved product intended to satisfy the various dietary habits. It does not appear that such a prohibition, although restricted only to product intended for sale on the domestic market of the state concerned, constitutes a means of arbitrary discrimination or disguised restriction on trade between MSs within the meaning of article 36."*[73] Hereby, the Netherlands was able to justify such prohibition pursuant the protection of health and life of humans. Certain analogy of *"uncertainties"* might be seen with the precautionary principle (see the chapter *Precautionary principle*).

Only recently Nisin was approved on the European level by the Commission Directive 2010/69/EU. It is stated that this substance may be present in certain cheeses as a result of

[70] Article 1(2) of Directive 89/107/EEC
[71] Case 53/80 Officier van justitie v Koninklijke Kaasfabriek Eyssen BV Reference for a preliminary ruling: Gerechtshof Amsterdam - Netherlands [1981], para. 1-7
[72] Nisin is an antibiotic formed by certain types of lactic bacteria and occurs naturally in varying quantities in most varieties of cheese. It has the property of preserving the product for a longer period by retarding the process of deterioration due to the presence of butyric bacteri.
[73] Ibidem, para. 16

fermentation process.[74] Such disputes might only be eliminated by such uniform sets of rules adopted by the European Union. Otherwise MSs retain a discretionary power to decide which additives are prohibited if they might present danger to public health. For a stronger approach to additives in products see, especially, *Beer*[75] and *Sandoz*[76] case.

Chemicals

Chemicals represent a serious threat to health and life of humans, animal and plants. Therefore, the CJEU had to deal with prohibitions on certain chemicals and their possible impact on health and life of humans. These chemical elements and their compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used[77] are dedicated to cause particular chemical processes and chemical effects and are not intended for human consumption as medical products or additives as mentioned above.

Usage of trichloroethylene in industrial processes was the essential question in a so-called *Toolex*[78] case. Swedish regulation prohibited sale, transfer or any use, for industrial purposes, of chemical products composed wholly or partially of trichloroethylene. Toolex, a manufacturer of machine parts which are used in the production of compact discs, used trichloroethylene to remove residues of grease produced during the manufacturing process.

The CJEU confirmed repeatedly that national legislation, such as that at issue in the case, constitutes, in principle, a measure having an effect equivalent to a quantitative restriction. The Swedish Government submitted that *"trichloroethylene affects the central nervous system, the liver and kidneys. The fact that it is highly volatile increases the chances of exposure in circumstances that might result in damage to health. Inhaling the substance can cause fatigue, headaches, and difficulties with memory and concentration."*[79]

Even though such a total ban with certain exemptions is likely to reduce the volume of imported trichloroethylene, the CJEU clearly expressed that this measure is proportionate and does not go beyond what is necessary to achieve the legitimate objective.

The CJEU held: *"In light of the foregoing considerations, national legislation which lays down a general prohibition on the use of trichloroethylene for industrial purposes and*

[74] Commission Directive 2010/69/EU of 22 October 2010 amending the Annexes to European Parliament and Council Directive 95/2/EC on food additives other than colors and sweeteners.
[75] Case 178/84 Commission of the European Communities v Federal Republic of Germany [1994]
[76] Case 174/82 Criminal proceedings against Sandoz BV - Reference for a preliminary ruling: Arrondissementsrechtbank 's-Hertogenbosch – Netherlands [1983]
[77] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
[78] Case C-473/98 Kemikalieinspektionen v Toolex Alpha AB [2000], para. 14
[79] Ibidem, para. 41

establishes a system of individual exemptions, granted subject to conditions, is justified under Article 36 of the Treaty on grounds of the protection of health of humans."[80]

Therefore, it is easy for a MS to justify the prohibition on certain chemicals if there is a clear proof that such chemicals have severe effect on human health and environment. In this case the studies of the International Cancer Research Agency, set up by the World Health Organization, were used as evidence in order to prove that trichloroethylene is a carcinogen. The European Chemicals agency was then set up in order to implement the EU's chemicals legislation, to secure the safe use of chemicals, to provide information on chemicals and to address chemicals of concern.[81]

Alcohol

A separate subchapter must be devoted to alcohol and its possible danger to public health due to its specific character, different from previous products. The CJEU had to deal with Sweden national law which conferred on a State-owned company specially constituted for the purpose of monopoly over retail sales in Sweden of wine, strong beer and spirits and under which private individuals were prohibited from importing alcoholic beverages.[82] The main legal proceeding was initiated due to the fact that cases of bottles of wine produced in Spain were imported into Sweden without being declared to customs and were confiscated on the ground that they had been unlawfully imported in contravention of the aforementioned law. The appellants in the main proceedings declared that the prohibition in principle prevented all residents from directly importing alcoholic beverages into Sweden.

Therefore, the preliminary question was aimed at the question if such a measure can be justified on the ground of protection of health and life of humans. The CJEU emphasized: *"that legislation which has as its objective the control of the consumption of alcohol so as to prevent the harmful effects caused to health of humans and society by alcoholic substances, and which thus seeks to combat alcohol abuse, reflects health and public policy concerns recognized by Article 36 TFEU."*[83] Unfortunately, such a national rule could not enjoy benefits of derogation provided by the art.36 of TFEU because the society could have been protected from undesired effects of high alcohol consumption by less restrictive measures. The CJEU stipulated: *a measure under which private individuals are prohibited from importing alcoholic beverages,*

– *as it is unsuitable for attaining the objective of limiting alcohol consumption generally, and*

[80] Ibidem, para. 49
[81] http://echa.europa.eu/about-us;jsessionid=F0B3EA80E0700FC07E82B59EDD7A6CB6.live1
[82] Case C-170/04 Rosengren and Others v Riksåklagaren [2007], para. 6-15
[83] Ibidem, para. 40

– *as it is not proportionate for attaining the objective of protecting young persons against the harmful effects of such consumption,*

cannot be regarded as being justified under Article 30 EC on grounds of protection of the health and life of humans.[84] Thus, human health must be protected from harmful effects of alcohol consumption only by proportionate measures.

Restriction on advertising of alcoholic beverages is a sensitive issue. The CJEU held: *"it is in fact undeniable that advertising acts as an encouragement to consumption and that the disputed rules are not therefore a matter of indifference from the point of view of the requirements of public health recognized by art.36 of the Treaty."*[85] However, no discrimination or disguised restriction on trade between MSs can apply. French legislation imposed that restriction on advertising caused a distinction between domestic and imported products where imported products were subjects to more stringent provisions than those applicable to national products. The CJEU held: *"it authorizes advertising in respect of certain national products while advertising in respect of products having comparable characteristics but originating in other MSs is restricted or entirely prohibited."* [86] Therefore, France failed to fulfill its obligations. A total ban on advertising of alcoholic beverages is demonstrated below in the chapter *Total bans and the protection of health and life*. It is not disputed that high consumption of alcoholic beverages has a negative impact of public health but the principle of proportionality seems to be acting as a watchdog in such cases.

Others

Italian legislative decree subjected the marketing of foods, intended to meet the expenditure of intense muscular effort of sportsmen, to requirement of applying for a prior authorization of the Ministry of Health and to the payment of the costs entailed by the administrative handling of the application. Italian Government argued that the purpose of legislation in issue was to protect the health of consumer but was not able to show any alleged risk to public health which the products in question were likely to pose.[87] The CJEU emphasized that Italy *"failed to explain on what scientific data or medical reports the guidelines which it enclosed were based and has not given general information on those alleged risks."*[88] Simultaneously, Italian republic breached the principle of proportionality. Notification of marketing of the product in question would be less restrictive and sufficiently effective.

[84] Ibidem, para. 58
[85] Case 152/78 Commission of the European Communities v French Republic [1980], para. 17
[86] Ibidem, para. 18
[87] Case C-270/02 Commission of the European Communities v Italian Republic [2001], para. 4
[88] Ibidem, para. 24

The Italian authorities even prohibited the marketing of energy drinks, in particular those containing taurine and those containing caffeine in quantities exceeding certain limit. The Italian Government considered that an upper limit for caffeine is justified but again failed to show that such a prohibition on the marketing of energy drinks containing caffeine in excess of a certain limit is necessary and proportionate for the protection of public health. Therefore, the Commission's application was upheld and Italian Republic failed to fulfill its obligations under the Treaty.[89]

Greece enacted very strict regulations regarding the production of bread in order to protect public health by ensuring that hygiene requirements are complied with during the whole production process. A license had to be obtained in order to establish a bakery. This procedure applied also to *"the sale of products produced using the 'bake-off' method (quick thawing followed by re-heating or baking, at the sales outlets, of fully or partially pre-baked and frozen products),"*[90] and thus subjected the bake-off products with the same requirements as manufacturing a traditional bakery (as minimum floor area, lighting, ventilation *et al*.). Such a measure having equivalent effect could not be regarded as a selling arrangement as contemplated in *Keck and Mithouard* case, as it was disproportional and went beyond what was necessary to protect public health.[91]

To sum up, measures restricting the free movement of medical products, pesticides, additives, chemicals, alcohol or any other products must necessarily meet the requirement of proportionality and must be based on scientific data proving their negative impact on health and life of humans, animals or plants. These two elements are the most important in order to have a disputable measure justified.

Total bans and the protection of health and life

Well-settled case law of the CJEU demonstrates the approach to so-called *total bans* on advertisements, types of sale or import. Such total bans relate to prohibited ways of advertisements and sale and applies to all undertakings equally in a MS, and the doctrine of selling arrangements of *Keck and Mithouard* case could theoretically approve such a measure. However, the main question, in this matter, is if such total bans do not affect marketing of products from other MSs heavier than it affects the marketing of domestic products.

The most clarifying case regarding total bans is Swedish *Gourmet International*

[89] Case C-420/01 Commission of the European Communities v Italian Republic [2003], para. 36
[90] Joined Cases C-158/04 and C-159/04 Alfa Vita Vassilopoulos AE, formerly Trofo Super-Markets AE And Carrefour Marinopoulos AE v Elliniko Dimosio, Nomarchiaki Aftodioikisi Ioanninon [2006], Summary
[91] Ibidem, para. 27-28

Products[92] case. Sweden regulated the advertising of alcoholic beverages due to health risks of alcohol consumption and stated: *"Advertising may not be used to market alcoholic beverages on radio or television"*and *„advertising may not be used to market spirits, wines or strong beers either in periodicals or in other publications subject to the Regulation on Press Freedom and comparable to periodicals by reason of their publication schedule. That prohibition does not however apply to publications distributed solely at the point of sale of such beverages. "*[93] Gourmet International Products AB was therefore subsequently prosecuted due to three pages of advertisements for alcoholic beverages in one particular magazine. The CJEU refused to agree that such a measure is applied equally among producers because it is *"liable to impede access to the market by products from other Member States more than it impedes access by domestic products"*[94]. The main factor is the familiarity of the population of a MS with its own domestic products and it makes it impossible for a foreign producer to present his products on such a market. The observation of the Commission is very appropriate as it claims that *"for various, principally cultural, reasons, domestic producers have easier access to that means of advertising than their competitors established in other Member States."*[95] To sum up, such bans affect products from other MSs heavier than the domestic products and thus they constitute measures having equivalent effect to quantitative restrictions. These measures may be justified by the protection of health and life pursuant to the art.36 of TFEU only if they meet the principle of proportionality. The CJEU leaves the evaluation of the possibility to achieve protection of health and life by less restrictive measures to the national court which is in a better position regarding the circumstances of law and facts.

A total ban on sale by mail order of medicinal products, which are not subject to medical prescriptions in a MS, cannot be justified pursuant to the art. 36 of TFEU as it goes beyond what is necessary to achieve the legitimate objective.[96] A total prohibition against advertisements aimed at children cannot be justified as well because such a prohibition is not in compliance with the *"television without frontiers"* directive and such an outright ban might has a bigger impact on products from other Member States.[97]

Even the German prohibition on the import of meat products from other MSs, manufactured from meat not coming from the country of manufacture of the finished product,

[92] Case-405/98 Konsumentombudsmannen (KO) v Gourmet International Products AB (GIP). - Reference for a preliminary ruling: Stockholms tingsrätt – Sweden [2001], para. 4
[93] Ibidem, para. 4
[94] Ibidem, para. 21
[95] Ibidem, para. 24
[96] Case C-322/01 Deutscher Apothekerverband eV v 0800 DocMorris NV and Jacques Waterval [1983], para. 1 in Operative part
[97] Joined cases C-34/95, C-35/95 and C-36/95 Konsumentombudsmannen (KO) v De Agostini (Svenska) Förlag AB (C-34/95) and TV-Shop i Sverige AB (C-35/95 and C-36/95) [1997], para. 62

was found unacceptable and disproportionate to the objective of protection of health and life.[98] Moreover, the prohibition on the importation into its territory of pasteurized milk and unfrozen pasteurized cream from other MS is extremely disproportionate.[99]

Such total bans are about to affect imported goods more heavily and creates advantageous position for domestic products which are well-known among domestic population. The free movement of goods is secured only if domestic products and products stemming from other MSs have the same conditions regarding the free and fair competition. These total bans distort or completely exclude the competition between products. The CJEU is not in favor of such total bans but admits their compliance with the Treaty only if the protection of health and life could not have been achieved by less restrictive measures.

Precautionary principle

This principle is one of the main approaches regarding the protection of health and life pursuant to the art.36 of TFEU. The CJEU provides its clear demonstration in the outstanding *Sandoz* case[100] embedding this principle in the case law.

Regarding the matter of facts, pursuant to the Netherlands' decree no vitamins may have been added to food and beverages without an authorization granted by the minister responsible for its implementing. Criminal proceedings were brought against Sandoz BV, for having sold and delivered in the Netherlands for commercial purposes and for consumption, without such authorization, food and beverages to witch vitamins had been added – namely muesli bars and analeptic beverages with vitamins A and D, even though they were lawfully marketed in Germany. Application for authorization was rejected on the ground of a danger to public health. There is no doubt that these national rules are measures having an effect equivalent to quantitative restrictions what was confirmed by the CJEU.[101]

Therefore, the main question is whether the art.36 of TFEU and its justification on the ground of protection of health and life of humans, animals or plants is applicable. The most difficult part is the evaluation of real risk of vitamins added to foodstuff. The Netherlands contended that the disputable measure had been necessary to protect health from risk of vitamins for prolonged period in high doses or from malnutrition.

The decisive part of this decision lies in scientific uncertainty of the harmfulness of the

[98] Case 153/78 Commission of the European Communities v Federal Republic of Germany [1979], para. 16
[99] Case 261/85 Commission of the European Communities v United Kingdom of Great Britain and Northern Ireland [1988], para. 19
[100] Case 174/82 Criminal proceedings against Sandoz BV. - Reference for a preliminary ruling: Arrondissementsrechtbank 's-Hertogenbosch – Netherlands [1983], para. 1-5
[101] Ibidem, para. 1-5

abovementioned vitamins. When and in what quantities are these vitamins harmful? The CJEU confirmed: *"Excessive consumption of them over a prolonged period may have harmful effects, the extend of which varies according to the type of vitamin."*[102] Simultaneously, it emphasized: *"Scientific research does not appear to be sufficiently advanced to be able to determine with certainty the critical quantities and the precise effects."*[103] No party to the dispute was able to prove the harmful effects of vitamin consumption but, simultaneously, none of them could exclude those effects as the consumers may consume them with other foods of further quantities of vitamins. Community legislature accepts the principle that food additives must be restricted but leaves the discretion to MSs to adopt rules thereof.

The CJEU held: *"In so far there are uncertainties at the present state of scientific research it is for the MSs, in the absence of harmonization, to decide what degree of protection of the health and life of humans they intend to assure, having regard however for the requirements of the free movement of goods within the Community."*[104]

The CJEU justified national rules prohibiting, without prior authorization, the marketing of foodstuff to which vitamins have been added pursuant to the art.36 of TFEU on the ground of uncertainties in scientific research. The whole risk assessment was based on scientific uncertainty and might be understood as a pre-emptive measure to prevent any possible harm to human health that may occur due to the consumption of vitamins added to foodstuff. Therefore, it must be pointed out, that uncertainty is an immanent part of the precautionary principle and the measures are justified until scientific research provides proper data.[105]

Due to the vague level of scientific proof regarding possible negative effect of vitamins' surplus, the CJEU provides MSs with wide discretion "*in order to observe the principle of proportionality, authorize marketing when the addition of vitamins to foodstuff meets a real need, especially a technical or nutritional one."*[106] Uncertainties in scientific research relating to medical impact on human health were thus able to justify the aforementioned measures.

This was also confirmed in the *Michel Debus* case where the CJEU held: *"In view of the uncertainties in the present state of scientific research in the matter of food additives and of the absence of complete harmonization of national legislation, Articles 30 and 36 of the Treaty do not preclude national legislation restricting the use of such substances and laying down a*

[102] Ibidem, para. 11
[103] Ibidem, para. 11
[104] Ibidem, para. 16
[105] Antonopoulou L., Meurs P.V, The precautionary principle within European Union public health policy The implementation of the principle under conditions of supranationality and citizenship,Department of Economics, Aristotle University of Thessaloniki, 0168-8510/03/$ - 2003 Elsevier Ireland Ltd. doi:10.1016/S0168-8510(03)00049-6, page 183
[106] Case 174/82 Criminal proceedings against Sandoz BV. - Reference for a preliminary ruling: Arrondissementsrechtbank 's-Hertogenbosch – Netherlands [1983], para. 19

maximum limit on the use of a specific additive in certain products."[107]

However, the *precautionary principle*[108] was modified consequently by a sufficiently rigorous risk assessment doctrine.

Sufficiently rigorous risk assessment doctrine

The CJEU subsequently modified the precautionary principle to a "*sufficiently rigorous risk assessment doctrine"*. This new approach was achieved in *Dutch Vitamins*[109] case where Dutch legislation prohibited the addition of certain vitamins to foodstuffs. The CJEU in this case underlines the principle of proportionality and what is actually necessary to ensure the safeguarding of public health.

The CJEU adjudicated in paragraph 52: *„It must therefore be accepted that a Member State may, in accordance with the precautionary principle, take protective measures without having to wait until the existence and gravity of those risks become fully apparent (see, to that effect, National Farmers' Union, paragraph 63). However, the risk assessment cannot be based on purely hypothetical considerations*[110].

Therefore, the CJEU held that "*a proper application of the precautionary principle requires the identification of the potential negative consequences for health of the proposed addition of nutrients, and secondly a comprehensive assessment of the risk for health based on the most reliable scientific data available and the most recent results on international research*."[111] In order to successfully justify restrictions on the free movement of goods based on protection of health, MSs must present the precautionary principle as mentioned above and provide real risk assessment based on scientific studies and therefore scientific uncertainty only is not sufficient. In the present case the Netherlands did not produce any scientific studies showing that any intake over recommended daily allowance might cause damage to health and did not prove the real risk for public health. The CJEU requires "*in-depth assessment"* of the possible risk on public health, only scientific theoretical hypothesis is not enough in order to justify measures prohibiting the marketing of fortified foodstuff.

Moreover, this attitude might be also seen in case *JJJ Van der Veldt*[112] where the CJEU

[107] Joined cases C-13/91 and C-113/91 Criminal proceedings against Michel Debus. - References for a preliminary ruling: Pretura circondariale di Pordenone et Pretura circondariale di Vigevano [1983], para. 1 in Summary
[108] NB: prevention is not the same as precaution, "*prevention is the remedy against the exposure with regard to a known harm, precaution is meant to avoid the mere possibility of suffering harm or loss." See* Costa L., Privacy and the precautionary principle, computer law & security review28(2012)14-24, Published by Elsevier Ltd., 2012, page 16
[109] Case C-41/02 Commission of the European Communities v Kingdom of the Netherlands [2004], para 5-8
[110] Ibidem, para. 52
[111] Ibidem, para. 53
[112] Case C-17/93 Criminal proceedings against J.J.J. Van der Veldt [1994], para. 17

stipulates: „*However, the risk must be measured, not according to the yardstick of general conjecture, but on the basis of relevant scientific research".* In every case competent national authorities shall protect interests stemming from art. 36 of TFEU *"in the light of national eating habits and with due regard to the results of international scientific research."*[113]A total ban on additives without exceptions or possibility for issuing authorization which meets especially technical purpose and are lawfully produced and marketed in another MS is not covered by justifications mentioned in art.36 of TFEU.[114]

To sum up, *"protective measures adopted under the safeguard clause may not properly be based on a purely hypothetical approach to risk, founded on mere suppositions which are not yet scientifically verified"*[115]. Scientific research must be understood mainly as exploratory work of the Scientific Committee for Food, the Codex Alimentarius Committee of the Food and Agricultural Organization of the United Nations (FAO) and the World Health Organization (WHO).[116]

What must be borne in mind is that this real risk assessment must be based on four main elements: hazard identification, hazard characterization, exposure assessment and risk characterization.[117] If a MS argumentation possesses all four of these elements properly, such a MS has a high chance to have its measures justified. Only hypothetical considerations about possible negative impact on human health and life are not sufficient in order to justify any disputable measures.

Hygiene

Pursuant to the jurisdiction of the CJEU, hygiene is a part of the protection of health and may justify measures which prohibit selling of products if they are not in compliance with State hygiene regulations. Confectionery Hygiene Regulation, requiring chewing gums which are put up for sale in vending machines in Austria to be packaged, was justified and the CJEU held that it constituted an adequate and proportionate measure for the protection of public health.[118] Even such a measure cannot be based only on purely hypothetical considerations and the real risk to public health must be established on the basis of recent scientific data available at the date of

[113] Case C-42/90 Criminal proceedings against Jean-Claude Bellon, Reference for a preliminary ruling: Tribunal de grande instance de Marseille – France [1990], para. 17
[114] Case 178/84 Commission of the European Communities v Federal Republic of Germany [1994], para. 44
[115] Case C-236/01 Monsanto Agricoltura Italia SpA and Others v Presidenza del Consiglio dei Ministri and Others [2003], para. 106
[116] Joined cases C-13/91 and C-113/91 Criminal proceedings against Michel Debus. - References for a preliminary ruling: Pretura circondariale di Pordenone et Pretura circondariale di Vigevano [1983], para. 17
[117] Regulation (EC) No 178/2002 of the Parliament and of the Council of 28 January2002 laying down the general principles and requirements of food law, establishing the European Food SafetyAuthorityand laying down procedures in matters of food safety, [2002], art.3
[118] Case C-366/04 Georg Schwarz v Bürgermeister der Landeshauptstadt Salzburg [2005], para. 15-17

adoption of the restrictive measure.[119] Austrian agency for health and protection of nutrition (*Österreichische Agentur für Gesundheit und Ernährungssicherheit)* provided the CJEU in this case with explanation that non-packaged goods are impaired by moisture or insects, in particular ants, within vending machine containers. For that reason products must be properly packed in order to protect human health from illnesses. Therefore, proportionate regulations, obliging products to comply with provision regarding proper hygiene, are possible to be justified.

Protection of health and life of animals

The protection of health and life of animals contains two main elements, i.e. protection of conservation of existence and protection of species or biodiversity.[120] In order to present the main approach of the CJEU towards the protection of health and life of animals, three most relevant and widely known cases, aiming at welfare of animals, are now to be discussed.

Danish bees

The most widely known case, regarding the protection of animals, is so called *Danish bees'*[121] case. The matter of facts relates to the criminal proceeding against Mr. Ditlev Bluhme for infringements of Danish legislation prohibiting the keeping of bees other than those of the subspecies *Apis mellifera* (Læsø brown bee) on the island. The aim of Danish legislation was to protect domestic Læsø brown bees and secure the maintenance of biodiversity through ensuring survival of this population. Mr. Ditlev Bluhme argued that this legislation is not in conformity with the free movement of goods. The prohibition of keeping bees other then the subspecies concerned applied only to the inland with total area of 114 km^2. Therefore, two main interrelated preliminary questions arose in this case:

1. Is a MS allowed to introduce such measures in order to protect maintenance of the abovementioned subspecies against eradication;
2. And if such a measure can be limited geographically only to a certain area.

Accused in the proceedings claimed that keeping bees other that Læsø strain does not threaten this subspecies.

The very first task of the CJEU was to clarify if a disputed measure in this particular case constitutes a measure having equivalent effect and if such a measure can be justified on the ground of protection of health and life of animals. *Ipso facto*, the concerned measure hindered

[119] Ibidem, para. 24
[120] Frenz W., Handbuch Europarecht, band 1 Europäische Grundfreiheiten, Springer-Verlag Berlin Heidelberg 2004, page 367
[121] Case C-67/97 Reference for a preliminary ruling: Kriminalretten i Frederikshavn – Denmark [1998]

importation of bees other then the Læsø species and thus precluded the trade. But the emerging question while using *Dassonville clause*, which defines measures as hindering directly or indirectly, actually or potentially intra-Community trade, is whether there is a real limitation of the trade between MSs.

The CJEU affirmed position of accused: *"In so far as Article 6 of the legislative measure at issue in the main proceedings involves a general prohibition on the importation onto Læsø and neighboring islands of living bees and reproductive material for domestic bees, it also prohibits their importation from other Member States, so that it is capable of hindering intra-Community trade. It therefore constitutes a measure having an effect equivalent to a quantitative restriction."*[122] It is a remarkable attitude of the CJEU because this prohibition applied only to a small island with 114 km² and nevertheless was able to hinder Intra-Community trade of the European Union having total area of more than 4 000 000 km².

Such a measure having an effect equivalent to a quantitative restriction could have been understood as a measure regulating selling arrangements applying to all relevant traders, affecting in the same manner in law and in fact marketing of domestic products and of those other MSs based on *Keck and Mithouard case*[123] However, this was rejected by the CJEU.

The legislation at issue was justified based on the protection of health and life of animals where the CJEU held: *"measures to preserve an indigenous animal population with distinct characteristics contribute to the maintenance of biodiversity by ensuring the survival of the population concerned. By so doing, they are aimed at protecting the life of those animals and are capable of being justified under Article 36 of the Treaty."*[124]

Furthermore, the CJEU considered the measure at issue as proportionate where the prohibition applied to a specific area and in a non-discriminatory way. This case has two main peculiarities to be pointed out. The prohibition of keeping on the island bees other than those of the subspecies *Apis mellifera* applied indistinctly and on a very tiny specific area, and nevertheless the CJEU used art.36 of TFEU in order to justify this measure. The second peculiarity of this case is the area of the island which forms only marginal part of its whole surface. Thus, a measure on a tiny part of the MSs is able to influence the trade between MSs. Maintenance of biodiversity becomes hereby an imminent part of protection of health and life of animals pursuant to the art.36 of TFEU.

[122] Ibidem, para. 19
[123] Joined cases C-267/91 and C-268/91 References for a preliminary ruling: Tribunal de grande instance de Strasbourg - France. Criminal proceedings against Bernard Keck and Daniel Mithouard. Denmark [1993], para. 16
[124] Case C-67/97 Reference for a preliminary ruling: Kriminalretten i Frederikshavn – Denmark [1998], para. 33

Freshwater crayfish

The Commission argued in a so-called *Freshwater crayfish*[125]case that German rules, regarding the prohibition on importation of freshwater crayfish, were incompatible with the Treaty because they impeded imports of live freshwater crayfish originating from other MSs or in free circulation and that these contentious measures went beyond what was necessary in order to protect native species of crayfish against diseases and the risks of faunal distortion. Germany wanted to protect health and life of animals and the preservation of native species by limiting possible proliferation of non-indigenous species in natural stretches of water in Germany so as to protect the genetic identity of local populations of crayfish against faunal distortion. The CJEU declared such a prohibition as incompatible with the art.36 of the TFEU because the protection of native species could have been achieved by less restrictive measures. Thus, the principle of proportionality is a decisive element when a MS wants to protect health and life of animals.

Live sheep

The CJEU had to deal with export licenses of the UK to Spain in *Hedley Lomas*[126] case. The UK Ministry of agriculture refused to grant Mr. Lomas licenses for the export of live sheep to Spain for slaughter on the ground that their treatment in Spanish slaughterhouses was contrary to Council Directive 74/577/EEC. Such a refusal was based on the conviction that a certain number of Spanish slaughterhouses were breaching the requirements embedded in the aforementioned directive. Such exports license system naturally constituted a quantitative restriction on exports in contrary to art.35 of TFEU and was strongly condemned by the CJEU. It held: *"Community law precludes a Member State from invoking Article 36 of the Treaty to justify a limitation of exports of goods to another Member State on the sole ground that, according to the first State, the second State is not complying with the requirements of a Community harmonizing directive."*[127] Thus, MSs are not allowed to impose export licensed due to the fact that a MS of import is not complying with harmonizing rules. The UK argued that export licenses were justified under the art.36 of the Treaty and were thus consequently compatible with the Community law. What must be borne in mind, and was also emphasized in this case, is that *"recourse to Article 36 is no longer possible where Community directives provide for harmonization of the measures necessary to achieve the specific objective which would be*

[125] Case C-131/93 Commission of the European Communities v Federal Republic of Germany [1978], para. 5, 13 & 27
[126]Case C-5/94 The Queen v Ministry of Agriculture, Fisheries and Food, ex parte: Hedley Lomas (Ireland) Ltd [1996], para. 2
[127] Ibidem, para. 14

furthered by reliance upon this provision."[128]

Protection of health and life on animals might thus be named in various cases as protection of conservation, protection of existence, protection of species or biodiversity, or protection of fauna against diseases. Principle of proportionality must be ensured in every case and disputable measures cannot go beyond what is necessary to secure welfare of animals. Pursuant to the jurisdiction of the CJEU, art.36 of TFEU might be applicable in order to justify an indistinctly applicable measure. Furthermore, MSs cannot invoke art.36 of TFEU in order to justify limitation of exports of goods to another MS due to the fact that a MS of import is not complying with the requirements of a Community/Union harmonizing directive.

Protection of health of animals vs. protection of domestic market

From September 1981, the UK has imposed a total ban on the imports of fresh, frozen or chilled poultrymeat, eggs and egg production into England, Wales and Scotland from all other MSs except Denmark and Ireland. The UK argued that these measures were essential in order "*to deal in a more effective way with the control of Newcastle disease in poultry."*[129] These measures were naturally qualified by the CJEU as measures having equivalent effect to quantitative restrictions and thus prohibited by the Treaty. The UK wanted to justify abovementioned measures according to the art.36 of TFEU arguing that this policy was aimed at protecting animal health with regard to the Newcastle disease.

The main issue in this case was the second sentence of the art.36 of TFEU which states that such measures cannot constitute a means of arbitrary discrimination or disguised restriction on trade between MSs. The UK imposed this ban on poultry products except Denmark and Ireland and thus created distinctions between MSs of the European Union. The CJEU noted that these measures were imposed in order to block, for commercial and economic reasons, imports of poultry products from other MSs and underlined the fact that there are less stringent measures for attaining the same result. *„It is possible to preserve the highest standard of freedom from Newcastle disease without completely blocking imports from countries where vaccine is still in use,"* therefore the UK by those measures, preventing imports poultry products, failed to fulfill its obligations.[130] The protection of domestic production of poultry was obvious. The principles of proportionality and non-discrimination were breached, so the CJEU could not justify such

[128] Ibidem, para. 18
[129] Case 40/82 Commission of the European Communities v United Kingdom of Great Britain and Northern Ireland [1982], para. 8
[130] Ibidem, para. 41

restrictions. This approach was strongly emphasized in *Henn and Darby*[131] case where the CJEU strictly remarked: *"the second sentence of art.36 is designed to prevent restrictions on trade mentioned in the first sentence of that article from being diverted from their proper purpose and used in such a way as either to create discrimination in respect of goods originating in other MSs or indirectly to protect certain national products."* The UK focused on its interests on the protection of national products more than on actual Newcastle disease. Means of arbitrary discrimination or disguised restriction are fully unacceptable.

Prohibition on use and the protection of health and life

This is a rather new and specific approach of the CJEU where the importation of the products is not prohibited, but the use itself is not allowed due to the protection of health and life. The well-known principle of mutual recognition stemming from *Cassis de Dijon*[132] is thus impaired. The CJEU held in this particular case: *"there is no valid reason why, provided that they (goods) have been lawfully produced and marketed in one of the MSs,… , the sale of such products may not be subject to an legal prohibition on the marketing…"* Therefore a MS shall accept products lawfully marketed in another MS. But is the prohibition on use in compliance with the mutual recognition principle?

This confusion provides Case C-110/05 Commission of the European Communities v Italian Republic where the CJEU held: *"A Member State which, for reasons of road safety, prohibits mopeds, motorcycles, motor tricycles and quadricycles from towing a trailer specially designed for them and lawfully produced and marketed in other Member States has not failed to fulfill its obligations under Article 28 EC."*[133]

Commission argued that the prohibition on motorcycles towing trailers constituted a failure to fulfill obligations under the Treaty and after formal notice decided to institute the proceedings in front of the CJEU. The disputable Highway Code of Italy set forth: *"only automobiles, trolleybuses (vehicles with an electric motor not travelling on rails which take their energy from an overhead contact line) and automobile tractors (three wheeled motor vehicles intended to tow semi-trailers) are allowed to tow trailers."*[134]

Therefore, such a prohibition *de iure* and *de facto* respects the importation of products of another MS to the national market but the principle mutual recognition of products, lawfully manufactured and marketed in another Member State, is derogated because they were lawfully produced and marketed in the originating MS but they are not allowed to meet their purpose in a

[131] Case 34/79 Regina v Maurice Donald Henn and John Frederick Ernest Darby [1991], para. 3 in Summary
[132] Case 120/78 Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein [1979], para. 14
[133] Case C-110/05 Commission of the European Communities v Italian Republic [2005], para. 2 in Summary
[134] Ibidem, para. 8

MS of import.

Pursuant to the decision of the CJEU, this disputable act constituted a measure having equivalent effect to quantitative restrictions on imports within the meaning of Treaty. Such a prohibition on use was, however, justified in order to meet imperative requirements.[135] Thus the road safety, in other words the protection of health and life of human beings, is capable of justifying a hindrance of the free movement of goods. The CJEU held: *"In the absence of fully harmonizing provisions at Community level, it is for the Member States to decide upon the level at which they wish to ensure road safety in their territory, whilst taking account of the requirements of the free movement of goods within the European Community."*[136] The aforementioned measure, restricting the free movement of goods, was held as being appropriate for the purpose of ensuring road safety.

In other words, the combination composed of a motorcycle and a trailer is, according to Italy, a danger to road safety and such a prohibition is about to achieve the legitimate objective. *"Prohibition on motorcycles towing trailers specially designed for them and lawfully produced and marketed in Member States other than the Italian Republic must be regarded as justified by reasons relating to the protection of road safety."*[137]

This might be problematic because of several factors within the decision. Firstly, does the doctrine of mutual recognition have the same value nowadays as after *Cassis de Dijon* case? Trailers as goods at issue were lawfully produced in one MS meeting all safety requirements and therefore the producer could await its legal introduction into Italian market. Do not the prohibition on use and the prohibition on imports have the same impact – preventing customers from buying a product? The principle of legal certainty and legitimate expectations might be a reasonable question after delivering the abovementioned judgment.

Another example is a preliminary question which was raised in the legal proceeding against Mr. Mickelsson regarding national regulations precluding usage of personal watercraft (as jet-skis) on waters other than designated waterways and regarding application of art.34 and art.36 of TFEU. Mr. Mickelsson operated personal watercraft on waters other than general navigable waterways.[138] The CJEU held that such national measures create an obstacle to the free movement of goods and must be regarded as measures having equivalent effect to quantitative restrictions on imports for the purpose of art.34 of TFEU.

Such a national regulation has an impact on customer's intention to buy personal

[135] Ibidem, para. 59
[136] Ibidem, para. 61
[137] Ibidem, para. 69
[138] Case C-142/05 Åklagaren v Percy Mickelsson and Joakim Roos Reference for a preliminary ruling from the Luleå tingsrätt, [2005], para. 14

watercrafts when he knows that the usage of them is strictly limited. Personal watercrafts are thus prevented from specific and inherent purposes for which they were intended.[139] Such a measure might be justified only if it is proportionate to attain the protection of the environment or the protection of health. The CJEU put these two grounds on the same level having stated: *"As the protection of the environment, on the one hand, and the protection of health and life of humans, animals and plants, on the other hand, are, in the present case, closely related objectives, they should be examined together in order to assess whether regulations such as those at issue in the main proceedings are justified."*[140] Hereby, the CJEU proves that the distinction between protection of environment and protection of health is too difficult or sometimes even undesirable.

Unlike the previous case regarding road safety, in this case the CJEU held that these measures went beyond what was necessary to achieve protection of the environment and health of humans while generally prohibiting usage of such goods on water other than general navigable waterways. Simultaneously, the CJEU determines series of measures which are proportionate, i.e. implementing measures by the competent national authorities in order to designate waters other than general navigable waterways on which personal watercraft may be used; those authorities have actually made use of such a power and such measure must be adopted within a reasonable period after the entry into force of those regulations. The CJEU thereby provides alternative means to achieve the aim in question and leaves assertion of abovementioned conditions to national court which is in a better position to come up with a conclusion.

Paragraph 26 of the judgment sets forth: *"national regulations at issue do not have the aim or effect of treating goods coming from other Member States less favorably, ..., the restriction which they impose on the use of a product in the territory of a Member State may, depending on its scope, have a considerable influence on the behavior of consumers, which may, in turn, affect the access of that product to the market of that Member State"*[141] This particular paragraph of the decision clarifies that the *"prohibition on use"* is a trade barrier, and thus falls under the prohibition of art.34 of TFEU. *Ipso facto*, such a measure affects the access of the product to a MS due to the fact that it has an influence on the behavior of consumers. Moreover, this influence must be considerable. *"The threshold is crucial, but alarmingly elusive, and seems inevitably to point to messy case-by-case application".*[142]

[139] Ibidem, para. 27
[140] Ibidem, para. 33
[141] Ibidem, para. 26 & Case C-110/05 Commission of the European Communities v Italian Republic [2005], para. 56
[142] Weatherill S., Free movement of goods, International and Comparative Law Quarterly, 61, pp 541550 doi:10.1017/S0020589312000048, 2012, page. 542

In addition, Portugal was unsuccessful when trying to justify, by the objectives of road safety and public safety, the prohibition on the affixing of any type of tinted film designed to filter light to the windscreen and the windows alongside the passenger seats in motor vehicles. Such a measure was intended to ensure public safety and road safety but was not in conformity with the principle of proportionality. The CJEU held: *"that at least some films, namely those with a sufficient degree of transparency, permit the desired visual inspection of the interior of motor vehicles"*, and thus the measure was regarded as excessive. [143]

Prohibitions on use are strong trade barriers if they considerably influence the behavior of customers and are prohibited pursuant to the art.34 of TFEU. They undermine the principle of mutual recognition and cause huge confusion among producers. They should be justified only in exceptional cases where the objective cannot be achieved by less restrictive measures.

Double requirements

Excessive double controls of products due to the crossing of frontiers are prohibited if those products have already met all necessary requirements of the country of origin. In *UHT Milk*[144] case the UK introduced the system under which the UHT milk[145] imported from another MS is subject to a system involving a second heat treatment and its repacking. This means that UHC milk imported into the UK has to be repacked in premises within the UK, what makes it necessary to retreat that milk again, since it is technically impossible to open the packs and to repack the milk without losing its characteristics. The CJEU emphasized that: *"product to a second heat treatment causes delays in the marketing cycle, involves the importer in considerable expense and, moreover, is likely to lower the organoleptic qualities of the milk."*[146] Such a system was found as a measure having equivalent effect to quantitative restrictions. The UK argued that such a system is about to protect health of humans and such a control is "*indispensable for ensuring that the milk obtained is free of any bacterial or virus infection."*[147] This must be understood as a prohibition on imports because it makes it impossible for importers to fulfill all the requirements and simultaneously be competitive. The UK applied such a measure even though the producers met all the requirements in the country of origin in order to produce

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[143] Case C-265/06 Commission of the European Communities v Portuguese Republic [2008], para. 46-48
[144] Case 124/81 Commission of the European Communities v United Kingdom of Great Britain and Northern Ireland [1983]
[145] "Ultra heat treated" process, whereby the product id retained at a temperature considerably in excess of 100* centrigrade for a short time, enables milk so treated to be kept for several months at room temperature, provided that, directly after the treatment, it is aseptically packed in hermetically-sealed containers.
[146] Ibidem, para. 21
[147] Ibidem, para. 24

milk harmless for human health. Therefore, the UK failed to fulfill its obligation due to the system of prior individual licenses for imports onto its territory and making such milk a subject to system involving a second heat treatment and the repacking of the milk. The CJEU does not accept arguments regarding the protection of health and life if the product was produced properly in the originating state. Measures in this dispute did not comply with the principle of proportionality and the principle of mutual recognition.

Prohibition on importation of medicinal products, simply because they did not comply with the labeling requirements and did not provide package leaflets in accordance with legal requirements, the CJEU found unjustifiable because those products were legally marketed in another MS with marketing authorization. The CJEU held: *"prohibition on the importation of the products in question… is not necessary for the effective protection of human health and life."*[148]

Imposing such double requirements on products, legally produced and marketed in another MS, is disproportionate and cause excessive costs distorting the competition between products. The aforementioned cases went extremely beyond what was necessary to protect health and life of humans.

Labeling requirements

Case law of the CJEU demonstrates variety of different obstacles to the free movement of goods such as requirements to designation, form, size, weight, composition, presentation, labeling or packaging, even though these rules apply without distinction to all domestic and imported products. Requirements regarding the labeling of products may fall very easily under the prohibition unless they can be justified by a public-interest objective taking precedence over the free movement of goods.[149]

Warnings

The CJEU had to decide whether national linguistic requirements and requirements relating to packaging of cosmetic products constitute an obstacle to intra-Community trade.

German legislation obliged manufactures of cosmetic products to put the full wording of warnings relating to the proper usage of products on both packaging and the container in the official language of each country of distribution concerned. Unfortunately, the Schwarzkopf Company had included those warnings in full only on leaflets enclosed with the products

[148] Case C-347/89 Freistaat Bayern v Eurim-Pharm GmbH [1991], para. 35
[149] Case C-33/97 Colim NV v Bigg's Continent Noord NV [1999], para. 38

concerned and only the following abbreviated information in nine languages (German, French, Dutch, English, Spanish, Swedish, Italian, Portuguese and Arabic) appeared on the outer packaging and the container- *"For commercial use only. Important: follow instructions for use and heed warnings."*[150]

The CJEU strongly emphasized that such proper packaging is about to ensure the protection of health of professional users and their clients. The arguments that the products in question were intended exclusively for professional users, who use them daily and thus know how to do it properly, were rejected.

Therefore, measures imposing compulsory warnings in full on the container and packaging of a cosmetic product in the language of the Member State in which it is to be marketed are justified by the public interest objective of protecting public health.[151] Even though these products aimed at commercial use, the protection of professional users must be protected and the CJEU found this measure justifiable. Such labeling requirements are thus necessary to protect public health of professional users and their customers.

List of ingredients and misleading of customers

Measures imposing obligations related to providing lists of ingredients of a product aimed at consumption are justified by the CJEU. The CJEU confirmed that obligations imposed under the legislation of a MS to indicate the ingredients of compound feedingstuffs in descending order of their proportion, are justified by the protection of health of humans and animals within the meaning of art.36 of TFEU as well as by the requirements of consumer protection and fair trading.[152] Such a list had to be provided within the product in order to make stock farmers aware of the type and quantity of raw materials contained in the compound feedingstuffs. Furthermore, any indications and information regarding the product must be accurate and cannot mislead the customer. The Treaty does not preclude national legislation prohibiting the importation and marketing of a product whose name incorporates certain characteristics which it does not have and thus misleads the customer. It must be borne in mind that: *"information which is misleading as to the characteristics of such products could have an impact on public health."*[153] In order to determine whether such an information or indication is misleading the consumer or not, courts need to take into account *"the presumed expectations of an average consumer who is reasonably well-informed and reasonably observant and*

[150] Case C-169/99 Hans Schwarzkopf GmbH & Co. KG v Zentrale zur Bekämpfung unlauteren Wettbewerbs eV. [2001], para. 8-15
[151] Ibidem, para. 40-42
[152] Case C-39/90 Denkavit Futtermittel GmbH v Land Baden-Württemberg [1991], para. 25
[153] Case C-220/98 Estée Lauder Cosmetics GmbH & Co. OHG v Lancaster Group GmbH [2001], para. 25

circumspect."[154] Proper list of ingredients and proper information of the product are necessary for the protection of public health.

Package leaflets

On the other hand, measures regarding the labeling which obstruct the free movement of good and does not persuade the CJEU that they are sufficiently necessary to protect health, cannot be justified at all. A preliminary question was raised before the CJEU if the Treaty precludes MSs from adopting measures which make it impossible for an undertaking to import from another MS finished medical products if they do not comply with package leaflets in accordance with domestic provision. The argument that such measures are necessary for the effective protection of human health and life was rejected. The CJEU held: *"Treaty preclude national legislation from prohibiting the importation from another Member State of proprietary medicinal products legally marketed in that State when those products are subject to marketing authorization in the importing Member State and the importer holds a manufacturing permit for the purpose of labeling them and providing them with a package leaflet in accordance with the legislation of the importing Member State."* [155] Harmonizing rule stresses out that no medicinal product may be placed on the market of a Member State unless a marketing authorization has been issued by the competent authorities of that Member State and aforementioned measure burdened the free movement of goods which had already complied with all requirements in the State of origin.[156] In this case, package leaflets were in full compliance with regulations of the State of production and thus provided proper protection of health and life of humans. Requirements of labeling in the State of purchase imposed pointless double burden.

Written warnings, requirements regarding lists of ingredients and proper information of the product or package leaflets are of great relevance because they secure the proper contact of products with beneficiaries. Therefore, they must meet strict requirements which are necessary in order to protect human health. The principle of proportionality must be properly observed.

[154] Case C-210/96 Gut Springenheide GmbH and Rudolf Tusky v Oberkreisdirektor des Kreises Steinfurt [1998], para. 31
[155] Case C-347/89 Freistaat Bayern v Eurim-Pharm GmbH [1991], para. 36
[156] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, [2001], art.6

Protection of the environment and the free movement of goods

Protection of environment is one of the objectives of the European Union with legal background in art.191-193 of TFEU and the European Union environmental law has in a few decades become "*the main source of inspiration for national environmental law in the EU Member States."*[157] Art.191 of TFEU sets forth that European Union policy on environment shall contribute to preserving, protecting and improving quality of the environment, protecting human health, prudent and rational utilization of natural resources and promoting measures at international level to deal with regional and worldwide environmental and in particular combating climate change. *"Environmental protection and sustainable development continues to occupy a prominent place in the objectives of the European Union"*[158] and its environmental policy must be thus "*integrated into the definition and implementation of the Union policies and activities, in particular with a view to promoting sustainable development."*[159]

Protection of the environment is not included in the art.36 of TFEU but is very closely connected to the protection of health and life of humans, animals or plants, therefore special attention must be paid to it. The CJEU itself held: *"the objective of protection of health is therefore already incorporated, in principle, in the objective of protection of the environment."*[160]

What must be pointed out is that protection of environment is a broader term than the protection of health and life. The protection of environment is presented by most relevant cases demonstrated below.

A deposit-and-return system for bottles

The CJEU classified the protection of environment as a mandatory requirement. This was emphasized in a so-called *Danish bottles'* case[161] where the CJEU provided: *"Since the protection of the environment constitutes one of the Community's essential objectives, it is such a requirement".* This remarkable case, concerning the protection of environment, provides a clear approach of the CJEU. The matter of fact relates to all containers for beer and soft drinks which must be returnable. This requirement was obviously not challenged by the Commission but the

[157] Burgues J.G, Werner, KreinsY, Lavrysen L., Tiberghien F., A Common Heritage: ED Environmental Law and National Judges, Koninklijke Brill NY, LeiJen, 20ro DO!: 1O.1l63/16137271OX525109, Journal for European environmental & planning law, page 221

[158] Vedder H., Analysis The Treaty of Lisbon and European Environmental Lawand Policy, Journal of Environmental Law 22:2 _ The Author [2010]. Published by Oxford University Press, page 288, doi:10.1093/jel/eqq001 Advance Access published on 24 February 2010

[159] Art.11 of TFEU

[160] Case C-28/09 Commission of the European Communities v Republic of Austria [2011], para. 122

[161] Case 302/86 Commission of the European Communities v Kingdom of Denmark [1988], para. 1 in Summary

problematic question at issue was a provision of national law under which the containers had to be approved by the National Agency for the Protection of the Environment, which could refuse approval of new kinds of container, especially if it considers that a container was not technically suitable for a system for returning containers. Denmark provided that a "*deposit-and-return system is established, non-approved containers, except for any form of metal container, may be used for quantities not exceeding 3 000 hectoliters a year per producer and for drinks which are sold by foreign producers in order to test the market.*"[162] Denmark wanted to naturally justify such measures due to the protection of environment but it could have been achieved by means less restrictive than the trade between MSs. The most important feature of measures protecting the environment is that: *"they must not go beyond the inevitable restrictions which are justified by the pursuit of the objective of environmental protection."*[163]

These Danish measures were disproportionate and the CJEU held that failure to fulfill obligations of the Treaty occurred. Main reasons were that importers had to remanufacture containers of type which were already approved and that it would involve substantial additional costs or produce drinks in non-approved containers only up to 3000 hectoliters a year. Moreover, the protection of the environment could be also secured by the system for returning non-approved containers. Therefore, restriction of the quantity of products marketed by importers is disproportionate to the objective pursued.[164] Thus, production of bottles only according to the Danish standards is incompatible with the principle of the free movement of goods.

This case confirmed environmental protection as an essential objective of the European Union and it added for the first time a new mandatory requirement to the *Cassis de Dijon* list.[165] This was a great break-through in perceiving the protection of the environment in correlation with the free movement of goods. The protection of environment thus applies as a ground for justification for indistinctly applicable measures.

Prohibition on importation of waste

Walloon waste[166] case is an outstanding case providing clear relationship between the art.36 of TFEU and the doctrine of mandatory requirements. The contentious act of the Kingdom of Belgium prohibited the storage, tipping or dumping, or causing the storage, tipping or dumping in Wallonia of waste originating in another Member State or in a region of Belgium

[162] Ibidem, para. 3
[163] Ibidem, para. 11
[164] Ibidem, para. 21
[165] Jacobs F., The role of the European Court of Justice in the Protection of environment, Journal of Environmental Law (2006) Vol 18 No 2, 185–205, doi: 10.1093/jel/eql012. Advance Access publication 5 May 2006, page. 188
[166] Case C-2/90 Commission of the European Communities v Kingdom of Belgium [1992]

other than Wallonia and provided that the derogations from this prohibition may be granted only for a specific period of time and must be justified under serious and exceptional circumstances. European Commission contented that such provision was contrary to the free movement of goods and to Directives 75/442/EEC and 84/631/EEC.

The main issue in the presented case was the fact that the contested legislation applied generally to waste, without distinguishing between hazardous and non-hazardous waste, even though the Directive 84/631/EEC provides a comprehensive system (such as prior notification) which relates to shipments of hazardous waste with a view to its disposal. Therefore, hazardous waste was the subject of harmonization and thus the CJEU set forth: *"It must therefore be held that the contested Belgian rules, in so far as they preclude the application of the procedure laid down in the directive and introduce an absolute prohibition on the import into Wallonia of hazardous waste, are not consistent with the directive in question even though they provide that certain derogations may be granted by the relevant authorities".* [167]

Simultaneously, the CJEU put waste at the same legal level as any other goods when it confirmed that: *"recyclable and reusable waste has an intrinsic commercial value, possibly after being treated, constitutes "goods" for the purposes of the Treaty."*[168] Belgium wanted to justify those legislative measures as imperative requirements in order to protect the environment and public health. Belgium contended that *"in view of the abnormal large-scale inflow of waste from other regions for tipping in Wallonia, there was a real danger to the environment, having regard to the limited capacity of that region."*[169]

Firstly, the Kingdom of Belgium failed to fulfill its obligations when imposed an absolute prohibition on the storage, tipping or dumping in Wallonia of hazardous waste originating in another Member State and thus precluded the proper application of the aforementioned Directive. However, the Directive did not cover non-hazardous waste, and thus Belgium Government was free to introduce a measure regarding this type of waste. Application of the doctrine of imperative requirements and the protection of the environment was successful. Non-hazardous waste could not be imported neither from another MS, nor from another region of Belgium and thus applied indistinctly. Therefore, the Kingdom of Belgium was allowed to impose such a measure in order to protect the environment as that measure applied indistinctly and could not be regarded as discriminatory. This case thus upheld the approach of *Danish bottles case*.

[167] Ibidem, para. 21
[168] Ibidem, para. 23
[169] Ibidem, para. 31

Climate change

Another example of justification of restriction on the free movement of goods based on the protection of the environment is a well-known *PreussenElektra*[170] case where a contentious measure imposed obligation on electricity supply undertaking to buy all electricity produced from renewable energy sources within the scope of that statute and within the respective supply area of each undertaking concerned. The CJEU stressed that the use of renewable energy sources for producing electricity, which abovementioned measure is intended to promote, is useful for protecting the environment in so far as *„it contributes to the reduction in emissions of greenhouse gases which are amongst the main causes of climate change which the European Community and its Member States have pledged to combat"*[171].

However, this measure, with a clear purpose to protect the environment, was discriminatory. The CJEU strongly emphasized:*"an obligation placed on traders in a Member State to obtain a certain percentage of their supplies of a given product from a national supplier limits to that extent the possibility of importing the same product by preventing those traders from obtaining supplies in respect of part of their needs from traders situated in other Member States".* Therefore, the approach created in *Danish bottles* case, upheld in *Walloon waste* case, was inapplicable because the protection of the environment as a mandatory requirement shall apply to indistinctly applicable/non-discriminatory measures. However, the CJEU freely argued that such a measure was designed to protect the health and life of humans, animals and plants [172] and justified it. This is, however, disputable. It wisely used the clause: *"environmental protection requirements must be integrated into the definition and implementation of other Community policies",*[173] what is now the art.11 of TFEU. Hereby, the climate change, as immanent part of environmental protection, was used as a ground for justification of the disputable measure in order to protect health and life of all three main elements: humans, animals and plants. This case thus finds a way how to use the protection of environment as a ground for justification of distinctly applicable measure. Moreover, the CJEU underlined that obligation of European Union and its Member States to pursue provisions which they contracted by virtue of the United Nations Framework Convention on Climate Change and by virtue of the Protocol of the third conference of the parties to that Convention, done in Kyoto on 11 December 1997.

On the other hand, Austria failed to fulfill its obligations under the Treaty by prohibiting

[170] Case C-379/98 PreussenElektra AG v Schhleswag AG, in the presence of Windpark Reußenköge III GmbH and Land Schleswig-Holstein [2001]
[171] Ibidem, para. 73
[172] Ibidem, para. 75
[173] Ibidem, para. 76

lorries of over 7.5 tones carrying certain goods from using a section of the A 12 motorway in the Inn valley. Austria wanted to reduce emissions of pollutants influenced by human activity and improve air quality; therefore, it prohibited on the abovementioned motorway transport of wastes, logs, non-ferrous and ferrous ores, motor vehicles, marble and others. Such a measure affected 200 000 journeys a year and was regarded as a measure having equivalent effect to quantitative restrictions. The intention to reduce emission was not disputed in this case and the protection of the environment was emphasized. Nevertheless, it was noted that the intended objective could have been achieved by measures less restrictive (for instance permanent speed limit of 100km/h) than implementing the sectoral traffic prohibition.[174]

Finding the balance

Protection of the environment and the free movement of goods stand against each other because they have different objectives. Hence, certain balance must be found in order to secure the free movement of goods while having the environment protected. A very confusing situation arises when the CJEU justifies measures in order to protect the environment. The CJEU may very easily apply the protection of the environment as a mandatory requirement if a measure is indistinctly applicable. However, when a measure is distinctly applicable, only grounds listed in art.36 of TFEU can be applied and the protection of the environment is not one of them. In this case a tortuous way might be used – referring to the protection of health and life as embedded in art.36 of TFEU, while emphasizing that environmental protection must be integrated into the definition and implementation of the European Union policies and activities. This situation could be very easily solved by including the protection of environment into the art.36 of TFEU. The CJEU differentiate between distinctly or indistinctly applicable measures and in the case of distinctly applicable measure applies this tortuous way or, in some cases, the CJEU simply avoids this distinction. This unclear approach of the CJEU seems to cause substantial confusion.

[174] Case C-28/09 Commission of the European Communities v Republic of Austria [2011], para. 13-26 &151

Conclusion

This thesis provides an overall analysis of the jurisdiction of the CJEU in correlation with the primary and secondary law of the European Union in order to explicate the topic itself and enable a reader to correctly anticipate the outcome of a case relating to the protection of health and life of humans, animals and plants.

The paper focuses on four main areas: requirements for a disputable measure to be justified and to escape the prohibition under the Treaty (i), demonstration of State's necessity to adopt such measures (ii), prohibition on use as a strong trade barrier (iii), and the protection of environment interrelated with the protection of health and life of humans, animals and plants (iv).

Any quantitative restriction or measure having equivalent effect must meet the following requirements in order to be justified:

- Actual purpose of such measure must be the protection of health and life of humans, animals and plants;
- The measure is necessary for achievement of the protection of health and life of humans, animals and plants;
- It is proportionate and cannot go beyond what is necessary to achieve the legitimate objective;
- Protection of domestic market or a hidden economic interest is not the aim of the measure;
- Involved precautionary principle must be based on the rigorous risk assessment;
- The measure does not cause a means of arbitrary discrimination or disguised restriction on trade between MSs;
- It does not constitute excessive double control causing distortion of competition and increase of costs;
- It does not impose total bans on advertising or type of sale of a product;
- It does not cause the prohibition on use which considerably influences the customer not to buy a certain product;
- It is not already regulated by harmonizing rules of the European Union.

The CJEU, pursuant to its case law, justifies disputable measures if they meet aforementioned requirements. Simultaneously, a MS has the burden of proof and has to provide the CJEU with arguments defending such measures, mainly, its necessity, proportionality and its aim to protect the health and life of humans, animals and plants. If a MS fails to prove that a disputable measure could not have been achieved by less restrictive measures or if it fails to

prove that such measures meet the abovementioned requirements, the CJEU is then obliged to declare that MS has failed to fulfill its obligations under the Treaty.

Special attention was dedicated to measures constituting prohibition on use. Such measures do not prohibit the importation of a certain product but they prohibit or substantially limit its usage. These measures are strong trade barriers and they must be condemned by the CJEU unless they are absolutely necessary for the achievement of protection of health and life of humans, animals and plants. Otherwise, they undermine the principle of mutual recognition, principle of legal certainty and principle of legal expectations. Decision regarding prohibition of towing a trailer[175] lawfully produced in another MS might therefore seem erroneous and the CJEU should oppose all prohibitions on use which considerably influence the customer not to buy a particular product.

The protection of environment should be included in the art.36 of TFEU. The protection of environment is the objective of the European Union and should obtain the same value as other grounds for justification named in the art.36 of TFEU. Application of it only as a mandatory requirement, applicable to indistinctly applicable measures, is not sufficient. The CJEU is thus forced to use a very tortuous way in order to justify distinctly applicable measure as demonstrated in *PreussenElektra* case.

This thesis demonstrates the most relevant cases of the CJEU in conjunction with the primary and secondary law of the European Union and provides deep explanation of the topic. Tables included below are providing an abstract of the most important cases regarding the protection of health and life of humans, animals and plants and indicates whether measures were or were not justified.

[175] Case C-110/05 Commission of the European Communities v Italian Republic [2005]

Overview of the most relevant case law regarding the protection of health and life of humans, animals and plants		Justified	
Nr.	Matter of facts	**Yes**	**No**
1.	Prohibition of marketing of beers lawfully manufactured and marketed in another MS if they do not comply with Biersteuergesetz[176]		**x**
2.	Prohibition of sale of medical products by mail order which are subject to medical prescription[177]	**x**	
3.	Prohibition of the sale of all medical products by mail order, regardless of being subject to medical prescription[178]		**x**
4.	Legislations authorizing the sale of contact lenses only in shops which specialize in the sale of medical devices and prohibiting the sale of contact lenses via the Internet[179]		**x**
5.	Law laying down that a contract for the supply of medicinal products is subject to cumulative conditions whose effect is to make it impossible in practice for a domestic hospital to be supplied on a regular basis by pharmacies established in other Member States[180]		**x**
6.	Prior authorization procedure to personal imports of homeopathic medicinal products.[181]		**x**
7.	Refusing licenses for importation of drugs from another MS may be successfully justified if it is not based on the need to safeguard an undertaking's survival and that the protection of health and life of humans cannot be achieved by less restrictive measures.[182]	**x**	
8.	A monopoly for dispensing pharmacists possessing exclusive rights to sell medicinal and para-pharmaceutical products.[183]	**x**	
9.	Prohibiting the sale, placing in stock or store or use of any plant-protection product which was not authorized by *Bestrijdingsmiddelenwet* decree of Netherlands	**x**	

[176] Case 178/84 Commission of the European Communities v Federal Republic of Germany [1994]
[177] Case C-322/01 Deutscher Apothekerverband eV v 0800 DocMorris NV and Jacques Waterval [1983]
[178] Ibidem
[179] Case C-108/09 Ker-Optika bt v ÀNTSZ Dél-dunántúli Regionális Intézete [2010]
[180] Case C-141/07 Commission of the European Communities v Federal Republic of Germany [2008]
[181] Case C-212/03 Commission of the European Communities v French Republic [2005]
[182] Case C-324/93 The Queen v Secretary of State for Home Department, ex parte Evans Medical Ltd and Macfarlan Smith Ltd [1995]
[183] Case C-369/88 Criminal proceedings against Jean-Marie Delattre, Reference for a preliminary ruling: Tribunal de grande instance de Nice – France [1991]

10.	Prohibition on having in stock a quantity of apples intended for human consumption having potential danger to health due to presence of 1.0 milligram of the pesticide[184]	**x**	
11.	Prohibition of usage of Nisin[185]	**x**	
12.	Prohibition on sale, transfer or any use, for industrial purposes, of chemical products composed wholly or partially of trichloroethylene[186]	**x**	
13.	Law conferring on a State-owned company specially constituted for the purpose a monopoly over retail sales in Sweden of wine, strong beer and spirits and under which private individuals are prohibited from importing alcoholic beverages[187]		**x**
14.	Legislation imposing restriction on advertising cauing distinction between domestic and imported products where imported products are thus subjects to more stringent provisions than those applicable to national products.[188]		**x**
15.	Legislative decree subjecting the marketing of foods, intended to meet the expenditure of intense muscular effort of sportsmen, to requirement of applying for prior authorization of the Ministry of Health and to the payment of the costs entailed by the administrative handling of the application[189]		**x**
16.	Prohibition of the marketing of energy drinks, in particular those containing taurine and those containing caffeine in quantities exceeding certain limit[190]		**x**
17.	Law subjecting the bake-off products with the same requirements as manufacturing traditional bakery[191]		**x**

[184] Case 94/83 Criminal proceedings against Albert Heijn BV, Reference for a preliminary ruling: Arrondissementsrechtbank Haarlem – Netherlands [1984]
[185] Case 53/80 Officier van justitie v Koninklijke Kaasfabriek Eyssen BV Reference for a preliminary ruling: Gerechtshof Amsterdam - Netherlands [1981]
[186] Case C-473/98 Kemikalieinspektionen v Toolex Alpha AB [2000]
[187] Case C-170/04 Rosengren and Others v Riksåklagaren [2007]
[188] Case 152/78 Commission of the European Communities v French Republic [1980]
[189] Case C-270/02 Commission of the European Communities v Italian Republic [2001]
[190] Case C-420/01 Commission of the European Communities v Italian Republic [2003]
[191] Joined Cases C-158/04 and C-159/04 Alfa Vita Vassilopoulos AE, formerly Trofo Super-Markets AE And Carrefour Marinopoulos AE v Elliniko Dimosio, Nomarchiaki Aftodioikisi Ioanninon [2006]

18.	Prohibition of advertising on radio or television of alcoholic beverages due to health risks of alcohol consumption. It may be justified by the protection of health and life pursuant art.36 of TFEU if it meets the principle of proportionality[192]	**x**	
19.	A total prohibition against advertisements aimed at children[193]		**x**
20.	Prohibition on the import from other MSs of meat products manufactured from meat not coming from the country of manufacture of the finished product[194]		**x**
21.	Decree prohibiting the addition of vitamins to food and beverages without an authorization granted by the minister responsible for its implementing[195]	**x**	
22.	Prohibition of addition of certain vitamins to foodstuffs[196]		**x**
23.	A total ban on additives without exceptions or possibility for issuing authorization which meets especially technical purpose and which are lawfully produced and marketed in another MS[197]		
24.	Regulation, requiring chewing gums, which are put up for sale in vending machines, to be packaged[198]	**x**	
25.	Prohibition of the keeping on the island of bees other than those of the subspecies Apis mellifera (Læsø brown bee).[199]	**x**	
26.	Prohibition on importation of freshwater crayfish due to preservation of native species by limiting possible proliferation of non-indigenous species in natural stretches of water in Germany [200]		**x**
27.	Refusing of granting licenses for export of live sheep for slaughter on the ground that their treatment in another MS's slaughterhouses was contrary to Council Directive 74/577/EEC[201]		**x**
28.	Total ban on the imports of fresh, frozen or chilled poultrymeat,		**x**

[192] Case-405/98 Konsumentombudsmannen (KO) v Gourmet International Products AB (GIP). - Reference for a preliminary ruling: Stockholms tingsrätt – Sweden [2001]
[193] Joined cases C-34/95, C-35/95 and C-36/95 Konsumentombudsmannen (KO) v De Agostini (Svenska) Förlag AB (C-34/95) and TV-Shop i Sverige AB (C-35/95 and C-36/95) [1997]
[194] Case 153/78 Commission of the European Communities v Federal Republic of Germany [1979]
[195] Case 174/82 Criminal proceedings against Sandoz BV. - Reference for a preliminary ruling: Arrondissementsrechtbank 's-Hertogenbosch – Netherlands [1983]
[196] Case C-41/02 Commission of the European Communities v Kingdom of the Netherlands [2004]
[197] Case 178/84 Commission of the European Communities v Federal Republic of Germany [1994]
[198] Case C-366/04 Georg Schwarz v Bürgermeister der Landeshauptstadt Salzburg [2005]
[199] Case C-67/97 Reference for a preliminary ruling: Kriminalretten i Frederikshavn – Denmark [1998]
[200] Case C-131/93 Commission of the European Communities v Federal Republic of Germany [1978]
[201] Case C-5/94 The Queen v Ministry of Agriculture, Fisheries and Food, ex parte: Hedley Lomas (Ireland) Ltd [1996]

	eggs and egg production into England, Wales and Scotland from all other MSs except Denmark and Ireland[202]		
29.	Prohibition on mopeds, motorcycles, motor tricycles and quadricycles from towing a trailer specially designed for them and lawfully produced and marketed in other Member States[203]	**x**	
30.	Regulations precluding usage of personal watercraft (as jet-skis) on waters other than designated waterways[204]		**x**
31.	Prohibition of the affixing of any type of tinted film designed to filter light to the windscreen and the windows alongside the passenger seats in motor vehicles[205]		**x**
32.	System under which the UHT milk imported from another MS is subject to a system involving a second heat treatment and its repacking.[206]		**x**
33.	Legislation obliging manufactures of cosmetic products to put the full wording of the warnings relating the proper usage of the product on both the packaging and the container in the official language of each country of distribution concerned.[207]	**x**	
34.	Indication of the ingredients of compound feedingstuffs in descending order of their proportion of a product aimed on consumption[208]	**x**	
35.	Legislation prohibiting the importation from another Member State of proprietary medicinal products legally marketed in that State when those products are subject to marketing authorization in the importing Member State and the importer holds a manufacturing permit for the purpose of labeling them and providing them with a package leaflet in accordance with the legislation of the importing Member State.[209]		**x**

[202] Case 40/82 Commission of the European Communities v United Kingdom of Great Britain and Northern Ireland [1982]
[203] Case C-110/05 Commission of the European Communities v Italian Republic [2005]
[204] Case C-142/05 Åklagaren v Percy Mickelsson and Joakim Roos Reference for a preliminary ruling from the Luleå tingsrätt
[205] Case C-265/06 Commission of the European Communities v Portuguese Republic [2008]
[206] Case 124/81 Commission of the European Communities v United Kingdom of Great Britain and Northern Ireland [1983]
[207] Case C-169/99 Hans Schwarzkopf GmbH & Co. KG v Zentrale zur Bekämpfung unlauteren Wettbewerbs eV. [2001]
[208] Case C-39/90 Denkavit Futtermittel GmbH v Land Baden-Württemberg [1991]
[209]Case C-347/89 Freistaat Bayern v Eurim-Pharm GmbH [1991]

36.	A pecuniary charge levied for a compulsory public health inspection of raw hides as they cross the frontier[210]		**x**
37.	A deposit-and-return system where non-approved containers, except for any form of metal container, may be used for quantities not exceeding 3 000 hectoliters a year per producer[211]		**x**
38.	System of taxation on electricity according to the method of generation what means that electricity produced by environmentally friendly method is taxed less than electricity produced by methods harming environment where the flat rate of duty on imported electricity was calculated so as to correspond to the average rate levied on electricity produced in Finland[*212*]		**x**
39.	Prohibition of the storage, tipping or dumping or causing the storage, tipping or dumping in Wallonia of waste originating in another Member State or in a region of Belgium other than Wallonia[213]	**x**	
40.	Imposition of obligation on electricity supply undertaking to buy all electricity produced from renewable energy sources within the scope of that statute and within the respective supply area of each undertaking concerned.[214]	**x**	
41.	Prohibiting lorries of over 7.5 tones carrying certain goods from using a section of the A 12 motorway in the Inn valley[215]		**x**
42.	Prohibition on the importation into its territory of pasteurized milk and unfrozen pasteurized cream[216]		**x**

[210] Case 87-75 Conceria Daniele Bresciani v Amministrazione Italiana delle Finanze [1976]
[211] Case 302/86 Commission of the European Communities v Kingdom of Denmark [1988]
[212] Case C-213/96 Outokumpu Oy Reference for a preliminary ruling: Uudenmaan lääninoikeus – Finland [1998
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6. Council Directive 89/552/EEC of 3 October 1989 on the coordination of certain provisions laid down by Law, Regulation or Administrative Action in Member States concerning the pursuit of television broadcasting activities [1989]
7. Council Directive 74/577/EEC of 18 November 1974 on stunning of animals before slaughter [1974]
8. Directive 81/389/EEC establishing measures necessary for the implementation of Directive 77/489/EEC on the protection of animals during international transport [1981]
9. Council Directive 75/442/EEC of 15 July 1975 on waste [1975]
10. Council Directive 84/631/EEC of 6 December 1984 on the supervision and control within the European Community of the transfrontier shipment of hazardous waste [1984]
11. Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market[1998]
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13. Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) [2006]
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2. Case 2-73 Riseria Luigi Geddo v Ente Nazionale Risi [1973]
3. Case 15/79 P.B. Groenveld BV v Produktschap voor Vee en Vlees [1973]
4. Case 8-74 Procureur du Roi v Benoît and Gustave Dassonville [1974]
5. Case 155-73 Giuseppe Sacchi. - Reference for a preliminary ruling: Tribunale civile e penale di Biella – Italy [1974]
6. Case 87-75 Bresciani v. Administrazione Italiana delle Finanze [1976]
7. Case 87-75 Conceria Daniele Bresciani v Amministrazione Italiana delle Finanze [1976]
8. Case 7/78 Regina v Ernest George Thompson, Brian Albert Johnson and Colin Alex Norman Woodiwiss [1978]
9. Case C-131/93 Commission of the European Communities v Federal Republic of Germany [1978]
10. Case 120/78 Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein [1979]
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12. Case 152/78 Commission of the European Communities v French Republic [1980]
13. Case 249/81Commission of the European Communities v Ireland. [1981]
14. Case 53/80 Officier van justitie v Koninklijke Kaasfabriek Eyssen BV Reference for a preliminary ruling: Gerechtshof Amsterdam - Netherlands [1981]
15. Case 55/80 and 57/80 Musik-Vertrieb membran GmbH et K-tel International v GEMA [1981]
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28. Case 95/81 Commission of the European Communities v Italian Republic. [1988]
29. Case 302/86 Commission of the European Communities v Kingdom of Denmark [1988]
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32. Case C-42/90 Criminal proceedings against Jean-Claude Bellon, Reference for a preliminary ruling: Tribunal de grande instance de Marseille – France [1990]
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35. Case C-347/89 Freistaat Bayern v Eurim-Pharm GmbH [1991]
36. Case C-39/90 Denkavit Futtermittel GmbH v Land Baden-Württemberg [1991]
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43. Case C-17/93 Criminal proceedings against J.J.J. Van der Veldt [1994]
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45. Case 178/84 Commission of the European Communities v Federal Republic of Germany [1994]
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55. Case C-33/97 Colim NV v Bigg's Continent Noord NV [1999]
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60. Case C-270/02 Commission of the European Communities v Italian Republic [2001]
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70. Joined Cases C-158/04 and C-159/04 Alfa Vita Vassilopoulos AE, formerly Trofo Super-Markets AE And Carrefour Marinopoulos AE v Elliniko Dimosio, Nomarchiaki Aftodioikisi Ioanninon [2006]
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72. Case C-141/07 Commission of the European Communities v Federal Republic of Germany [2008]
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Summary

Kunak, J. - Justification of Restrictions on Imports or Exports of Goods on the Grounds of the Protection of Health and Life of Humans, Animals or Plants / Joint Programme of European Union law and Governance. Supervisor Prof. Dr. Ignas Vėgėlė – Faculty of Law, Mykolas Romeris University, 2012. – 65 pages.

The present master thesis strives to provide an analysis of the overall jurisdiction of the CJEU in correlation with the primary and secondary law in order to fully comprehend its approach towards justification of measures hindering the trade between MSs, yet aiming at protection of health and life of humans, animals or plants.

In order to reach this goal, author has divided the thesis into three main parts. The first two parts deal with explanation of free movement of goods and quantitative restrictions on imports and exports and all measures having equivalent effect, mandatory requirements and the concept of goods. The third, main part focuses on overall and detailed analysis and examination of the jurisdiction of the CJEU subdivided into several sections interpreting the most relevant and well-known cases.

This aforementioned part aims at pointing out all strict requirements interpreted in the case law of the CJEU which are necessary in order to have a disputable measure justified. It also demonstrates that a MS is successful in justifying a measure only having proved that the measure is absolutely necessary to attain the protection of health and life of humans, animals and plants, and does not aim at protecting its domestic market. Moreover, it proves that prohibitions on use are strong trade barriers under prohibition of art.34 of TFEU hindering the access of products into a MS. Finally, the paper aims to defend a need to include the protection of environment into the art.36 of TFEU in order to diminish the confusion between application of mandatory requirements and art.36 of TFEU.

Santrauka

Kunak J. – Importo ir Eksporto Prekių Ribojimo Pagrįstumo Sąlygos Žmonių, Gyvūnų ar Augalų Sveikatos bei Gyvybės Apsaugos Tikslais/ Jungtinė Europos Sąjungos Teisės ir Valdymo Programa. Vadovas Prof. Dr. Ignas Vėgėlė – Teisės Fakultetas, Mykolo Romerio Universitetas, 2012. – 65 puslapiai.

Šis magistro tiriamasis darbas yra skirtas išanalizuoti Europos Sąjungos Teisingumo Teismo jurisdikcijos suderinamumą su pirmine ir antrine Europos Sąjungos teise, siekiant suvokti laisvą prekybą tarp valstybių narių ribojančių priemonių, kuriomis siekiama apsaugoti žmonių, gyvūnų ir augalų gyvybę ir sveikatą, pateisinimą.

Siekiant įgyvendinti šį tikslą, autorius suskirstė tiriamąjį darbą į tris pagrindines dalis. Pirmosiose dviejose dalyse nagrinėjama teisė į laisvą prekių judėjimą ir kiekybiniai importo ir eksporto ribojimai, bei lygiaverčio poveikio priemonės, privalomieji reikalavimai ir prekių sąvoka. Trečioji darbo dalis skirta bendrai ir nuodugniai Europos Sąjungos Teisingumo Teismo jurisdikcijos analizei, išskiriant su tema susijusių ir gerai žinomų bylų paaiškinimus.

Šia, pagrindine, magistro tiriamojo darbo dalimi siekiama apžvelgti visus teismų praktikoje nurodomus griežtus reikalavimus, kurie pateisintų bylose ginčijamas ribojančiąsias priemones. Šitokia analizė parodo, kad valstybė narė gali sėkmingai pateisinti taikomas laisvą prekių judėjimą ribojančias priemones tik tuo atveju, jei šios priemonės yra skirtos apsaugoti žmonių, gyvūnų ir augalų gyvybę bei sveikatą, bet ne valstybės narės vidaus rinką. Magistro tiriamasis darbas taip pat įrodo, kad prekių naudojimo draudimas, remiantis Sutarties dėl Europos Sąjungos veikimo (toliau – SESV) 34 str., laikomas stipria prekybą tarp valstybių narių ribojančia kliūtimi. Galiausiai, siekiant padidinti takoskyrą tarp privalomųjų reikalavimų ir SESV 36 str. nurodomų ribojančias priemones pateisinančių pagrindų taikymo, autorius skatina įtraukti aplinkos apsaugą, kaip vieną iš SESV 36 str. elementų.

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