Dipartimento di Giurisprudenza

Cattedra di *European Internal Market*

THE IMPACT OF THE NEW GENERATION EU FREE TRADE AGREEMENTS ON FOOD SECURITY: CHALLENGES AND OPPORTUNITIES

RELATORE

Chiar.mo Prof.
Daniele GALLO

CANDIDATA

Sara BELARDO
Matr. 126113

CORRELATORE

Chiar.ma Prof.ssa
Maria Rosaria MAURO

ANNO ACCADEMICO 2017/2018

INDEX

Chapter 3) Free trade agreements, global governance of food safety standards and the role of the EU: between multilateralism and bilateralism

Introduction

The aim of the present work is to analyse the impact that the new generation EU Free Trade Agreements (FTAs), may have on the European Food Law framework, which is perhaps one of the most complex and well-done set of rules ensuring food safety.

The analysis, albeit undertaken from the point of view of food regulations, entails a wider scope: how to deal with the balancing between the need to ensure free trade and business' interests on the one hand and the protection of non-trade values, like food safety and consumer protection on the other.

It is undeniable that international trade increases global, regional and national wealth by allowing countries to export goods and services in which they enjoy a comparative advantage and to import those ones they cannot produce by themselves. Yet, as the present work will show, while achieving economic gains, social values like human health, animal welfare and food safety may be endangered by the imperatives of free trade.

Moreover, in a globalized economy, the increasing power of multinational corporations, the scientific developments in the biotechnology industry and new transportation methods, represent the key factors at the core of the recent phenomenon of the so-called global value chain, thereby food products produced in a certain country, may be processed in another one, and then consumed all over the world. Therefore, owing to such deep interconnection of the markets, the risk of contamination in one of the stages of the supply chain, as well as the lack of the due information on the label, are likely to put international, regional and domestic food safety under threat.

Since the food sector is the largest production sector in the European Union, through the years, the EU has developed a legal framework which, addressing all food issues in a very effective, efficient and coherent way, has placed the EU food market, in the top three of most regulated and well-functioning industrial sectors. Yet, from an economic prospective, the more technical and sanitary standards are in place, the more obstacles and costs business operators meet while pursuing free trade. It is exactly this

issue and the way how EU free trade agreements try to cope with it, the main object discussed in the present work.

Food law, in fact, is perhaps one the legal sectors where it is more likely that non-tariff barriers, like size, weight, composition, packaging and so on, are used and perceived as a disguised form of protectionism, adopted by States to defend their national production, discriminating against foreign products.

Therefore, the rationale of these FTA is to create an international legal system whose main purpose is to reduce obstacles to trade and to increase regulatory convergence between States, shaping a common legal framework, which at the same time is nor too burdensome for enterprises, neither too risky for human health and consumers.

The object of the present work is, in particular, the analysis of four FTAs, chosen on the basis of the economic and political relevance of the partners involved and of the economic and social impact of their conclusion: the Transatlantic Trade and Investment Partnership (TTIP) negotiated with the US from 2013 to 2016; the Comprehensive Economic and Trade Agreement concluded with Canada and provisionally applied since September 2017; the FTAs with Singapore (EUSFTA) and Vietnam (EUVFTA), whose negotiations have been finalized respectively in 2014 and 2015, in light of the EU strategy to strengthen its trade and investment relations with Southeast Asian countries.

Nowadays, in fact, a shift from "trade liberalization" to "trade regulation" is evident. Almost all over the world, trade in goods and services, investments, intellectual property and public procurement are more and more addressed by this type of Agreements, seeking to create deep integration partnerships, which go beyond the commitment to reduce customs tariffs.

The rationale at the core of this attitude towards bilateralism lies in the lack of progress of the multilateral negotiations in the framework of the WTO and in the feeling of dissatisfaction with the course of the Doha Development Round negotiations. Owing to disagreements concerning not only agriculture, but also non-tariff barriers, services

and other issues, in 2008 negotiations stalled and since this breakdown, despite repeated attempts to revive the talks, no steps forward have been done so far.

In the WTO system, the legal basis to create customs unions and free-trade areas is set forth in Article XXIV GATT 94', which provides for an exception to the most favoured nation clause. The new FTAs, having a smaller membership, are capable to address even those sectors where unanimity in the multilateral forum cannot be reach and to include "WTO plus" provisions, which go beyond the multilateral commitments.

For what concerns the food sector, the rationale of this approach lies in the limits of the WTO's legal system, where food safety is relevant only as far as is trade related and where, in the balancing between economic and non-economic issues, trade values have almost always ended up prevailing.

In the WTO, in fact, the relevant provisions addressing the international dimension of the food market are the Agreement on technical barriers to trade (TBT agreement) and the Agreement on sanitary and phytosanitary measures (SPS agreement). The latter recognizes the States' right to adopt sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health, while imposing limits to avoid a misuse of this right to the detriment of the market ideal.

The aim pursued by the SPS Agreement, in fact, is not promoting global food safety, but only preventing its Parties from adopting disguised protectionist measures under the guise of "protective policies". Therefore, the reason for incorporating "SPS plus" provisions in one of the FTAs' chapters, lies in the fact that the WTO rules on food safety have not produced the expected effects in terms of positive harmonization of food standards.

For what concerns the European Union, thanks to the advisory opinion 1/94, in 1995 both the Community and the Member States became part of the WTO, as original members. From its beginning, in fact, there was large agreement about the fact that the European internal market should be opened to products coming from outside the Union and able to export abroad its own goods, mainly food products. Yet, the deadlock of

the multilateralist process, has led to changes even in the EU, where, the Commission Communication "Global Europe", adopted in 2006 has marked a shift from multilateralism to bilateralism of the Common Commercial Policy.

Therefore, in light of this new strategy and even considering that a comprehensive and multilateral agreement addressing food safety has not been included in the WTO agenda, the EU has been discouraged from seeking multilateral solutions to food problems.

EU institutions, in fact, at least since the 1990s, have paid increasing attention to food safety issues and consumer protection. Albeit it may seem counterintuitive, food related case-law delivered by the European Court of Justice has played a pivotal role in the integration process of the EU and EU food law has an intimate connection with the origin and development of the leading principles of the EU internal market.

As it will be emphasized, the free movement of food, differently from the free circulation of other goods, had to face several obstacles to be fully achieved. Difficulties were due to the lack of a common notion of "food quality" all around Europe, as well as of specific provisions in the Treaties. Therefore, the key factors for shaping the food legal system as we know it today have been the establishment of the principle of mutual recognition in the *Cassis* case of 1979 and the development of justifications to derogate from the Treaty provisions. According to the first principle, products lawfully produced and marketed in one Member State, may not be kept out from another Member State, on the ground that they do not comply with its national rules. Yet, thanks to treaty derogations and mandatory requirements, created through the ECJ case-law, States are empowered to restrict trade to protect, *inter alia*, human health and consumers. It is exactly consumer protection the value which, has been recognized at the same time as a right in the EU Charter of Fundamental Rights, but also as the pillar at the core of EU food law.

It has been mainly the BSE crisis in the 1990s, also known as the 'mad cow disease' the event which marked the turning point from a marked-oriented approach to food

safety towards a consumer-oriented one, then sacred in the Regulation No 178/2002. Among the general principles of food law, the application of the precautionary principle in risk assessment and the "farm to fork" principle will be analyzed deeply in the present work, since they have often clashed with the science-based approach and a more market-oriented regulation, adopted in the WTO system as well as by third countries.

This work, in fact, dealing with the EU's WTO disputes, where European law is often in contrast with the international norms addressing food safety, and the public debate concerning CETA and TTIP, will clearly show how difficult is to reconcile divergent regulatory approaches, especially when it comes to the transatlantic trade.

It is with regard to this issue that the relevance of the EU Free Trade Agreements comes to the fore. In fact, since tariffs on trade between the EU on one side and U.S. and Canada are already low, the focus of the negotiating parties has shift towards the so-called "behind the border obstacles to trade" resulting, for instance, from differences in environmental and food safety policies. To address and align as far as possible these non-tariff barriers to trade, several trade-facilitating tools, like mutual recognition and harmonization of standards are provided. The first one relies on the idea that, as far as certain conditions are met, even different technical and sanitary regulations may achieve the same results. The latter implies efforts to align domestic rules to a single standard, thus requiring the States involved to adjust their regulations.

Obviously the wider is the existing gap between food cultures and public health policies, the more it will be hard to achieve regulatory convergence on such sensitive issues.

This is the reason why in the EU, where rigid food standards exist, civil society organizations and national governments have express concerns about the fact that addressing the transatlantic regulatory divide through regulatory cooperation may determine a race to the bottom of EU food safety.

Canada and US have very similar food policy regulations. They both consider the cost-benefit analysis as the leading principle of their decision-making process and are refractory to a precautionary approach. The idea that a food product is safe, unless scientific proof that any harm may derive from its consumption exist, creates a situation where business' interests matter more than safety. Moreover, the American trust towards the use of biotechnology in the food sector and of growth hormones by the meat industry uses to clash with the more precautious European attitude, where the approach of "better safe than sorry" lies at the core of its food safety policy.

Therefore, the aim of the present analysis is to assess whether the new generation of Free Trade Agreements is capable to overcome such differences and even contributing to a wider and positive harmonization of international food standards.

The structure of the present work is divided into three chapters.

The first one deals with the origin and development of EU food law, addressing the three dimensions of this phenomenon: food products as goods which freely circulate in the market, the development of substantive EU secondary law addressing only food staff and the international trade dimension of the European food system.

At the beginning, in fact, there was no legal distinction between food products and other types of goods and in both cases the aim pursued was the same: allowing them to freely circulate, by removing barriers to trade. Therefore, the analysis focuses on the main provisions addressing the free movement of goods, set in Part Three, Title II of the Treaty on the Functioning of the European Union (TFEU): Article 30 on the prohibition of customs duties and charges having equivalent effect; Article 34 prohibiting quantitative restrictions and measures having equivalent effect; Article 36 providing for treaty derogations to the free movement of goods.

The second paragraph describes how, since the 1960, in order to supplement the "negative integration" rules set forth in the Treaties, instruments of "positive integration" were gradually adopted, with the aim to enhance the functioning of the EU food market. Yet, it was only after the consumer trauma related to the outbreak of the

"mad cow" disease in the UK in the 1990s that the full implementation of EU food law is achieved.

Therefore, on the basis of the White Paper on Food Safety, laid down by the EU Commission in the 2000, the cornerstone of new European Food Law was adopted: Regulation 178/2002. By providing general principles and establishing the EFSA, its main task is to secure the safety of the EU food market and the precautionary principle, plays a key role in this regard.

The last paragraph of Chapter one discusses the third dimension of food law as shaped in the international legal framework of the WTO SPS Agreement. For what concerns the membership of the EU in the WTO, debate on the matter reached its height when on April 1994, the 125 Contracting parties of the GATT signed the Final Act embodying the results of the Uruguay Round multilateral trade negotiation. The ECJ advisory opinion 1/94 made clear that owing to the limits of what is now Article 207 TFEU, addressing the Common Commercial Policy, both the Community and the Member States became part of the WTO.

Yet, the analysis will clarify why, despite the initial enthusiasm, multilateral negotiations have failed, and which are the main reasons at the core of the current preference towards bilateral agreements.

The second Chapter will focus on the structure and objectives of the new generation Free Trade Agreements negotiated or concluded by the EU in light of its trade and investment strategy as defined in the two Commission's communications Global Europe and Trade for All adopted respectively in 2006 and 2015. The TTIP is the first one to be analyzed: negotiated from 2013 up to 2016 it was intended to create the largest free trade area of the world.

Yet, all over Europe the fear expressed has been that the conclusion of this agreement would have endangered EU food security. To address the rationale of these concerns, some famous WTO disputes between the EU and the US will be discussed: the 1996 Hormones case on the use of growth hormones in meat production; the EC-Biotech

disputes concerning the GMOs regulation and the chlorine-treated poultry case. All these cases make evident the divergent EU and US approaches to food safety and how difficult is to reconcile them.

The second FTA discussed is CETA, between EU and Canada. As well as for the TTIP, despite the economic potential of these mega-regional agreements concluded between economic and political leaders, the role of multinational corporations in the regulatory framework and the risk to reduce food safety standards to the lowest common denominator are the main issues at the core of public debate and will be discussed in detail. In particular, the case of the *Aquadvantage salmon,* concerning the placing on the Canadian market of the first GM salmon without labelling it as such, will show how wide is the regulatory gap between the EU and Canada.

The third part of chapter two will focus on the FTAs negotiated by the EU with Southeast Asian countries, namely Singapore (EUSFTA) and Vietnam (EUVFTA). Albeit these deals are not problematic from the point of view of food security, their relevance from an economic prospective is undeniable, since these countries are among the major trading partners in light of the EU's new trade strategy. Moreover, special attention is paid to the recent ECJ advisory opinion 2/15, which while addressing the debated issue concerning the nature of the EUSFTA as a "mixed" or "EU only" agreement, will have relevant impact on the future EU commercial policy.

The third chapter will seek to determine which is the role that FTAs play in the global governance of food security. Nowadays, in fact, owing to the limits of the WTO's multilateral dimension, a network of bilateral agreements incorporating multiple SPS-plus commitments seem the best solution for improving global food safety.

Moreover, the high quality of EU food law along with the DG trade's Strategic plan 2016-2020 which call up EU to play a stronger role as a global actor, may lead EU food standards to become a model worldwide. In this regard, FTAs could represent the best tool for promoting EU values beyond European borders and to shape global food standards in the best way.

Chapter I

European Food Market and its opening towards third countries

The three dimensions of food law

Eating and drinking are necessities of life and ensuring the safety of food and beverages is the main duty of food law. This is why, through the years, multi-layered rules ensuring food safety, have been more and more developed by all legal systems. Yet, in order to understand deeply the origin and development of such phenomenon, its three "dimentions" will be separately analized in the next three paragraphs: food products as goods which freely circulate in the market, the development of substantive EU secondary law addressing only food staff and the international trade dimension of the European food system.

The free movement of goods, in fact, leading cornerstone of the EU internal market and one of the pillars of international trade has always shown peculiarities when it comes to the food sector. While homologation of products was achieved thanks to the homogeneity of the making-processes and of results without any insurmountable difficulty, the free movement of food, as will be discussed later, had to face several obstacles[1]. Such impediments to trade have been addressed not only at the European level but also at the international one, mainly by the Agreement on Sanitary and Phytosanitary measures (SPS Agreement) in the context of the World Trade Organization.

Therefore, if there were no EU law, there would still be food law. However, "*if there was no food law, there certainly could not be EU law as we know it today*"[2]. This is because the Common Agricultural policy (CAP) first and EU food law then, have

[1] COSTATO L., *Il diritto alimentare: modello dell'unificazione europea* in *Rivista di Diritto Alimentare*, 2009, fasc. 3, p. 1

[2] BROBERG M., VELDE M., *The embedding of food law into substantive EU law* in VAN DER MEULEN B., *EU Food Law Handbook*, Wageningen, 2014, p. 39

played a key role in the European integration process, mainly through the case-law[3] of the European Court of Justice. By helping to detach non-tariff barriers to trade, its role has been pivotal for ensuring the well-functioning of the internal market. At the same time the establishment of the principle of mutual recognition in the *Cassis* case and the development of mandatory requirements to protect public goods have been the key factors for shaping the food legal system as we know it today.

Moreover, food scandals and related fraudulent practices in the 1990' led to a crucial shift in the European food law: from a market-oriented approach toward a system focused primarily on consumer protection and public health. Even the on-going globalization of the markets and the increasing phenomenon of the "global value chain", are likely to pose serious risks for consumers as wll as new challenges for food security and this is why focusing on the 'international trade dimension' of the European food system turns to be fundalmental.

In fact, even after the breakdown of the Doha negotiations in the context of the WTO and the development of the new European Free Trade Agreements the need to balance free trade on one side, while ensuring food safety and consumer protection on the other, is still one of the most debated issues.

This Chapter will discuss the three dimensions of food law. *The first* paragraph will deal with food products as goods subject to the leading principles of the EU internal market, as developed by the European Court of Justice. *The second* one will describe the origin and development of food law as shaped by EU secondary law and the need to ensure as far as possible food safety and consumer protection. *The tird one* will analyze the common commercial policy of the EU in the WTO framework and the way

[3] See, inter alia, *Procureur du Roi v. Dassonville*, Case 8/74, [1974] E.C.R. 837 *Rewe-Zentral AG v. Bundesmonopolverwaltung for Branntwein (Cassis de Dijon)*, Case 120/78, [1979] E.C.R. 649, 18, *Walter Rau v De Smedt*, 1982, case 261/81, ECR 3961, *Commission of the European Communities v Federal Republic of Germany*, *(Reinheitsgebot)*, 12 March 1987, Case 178/84, *Brasserie du pêcheur v Bundesrepublik Deutschland and The Queen / Secretary of State for Transport, ex parte: Factortame and Others*, 5 march 1996, Joined cases C-46/93 and C 48/93, C-79/78 *Racke*, 1979

how food safety has been addressed by the WTO SPS Agreement first and the Free Trade Agreement then.

1.1 The first dimention of food law: the free movement of food products as "goods"

EU food law, as we know it today, represents a large-scale reformulation, gradually undertaken through the years, of the previous system of EU rules on the free movement of goods. At the beginning, in fact, there was no legal distinction between food products and other types of goods and in both cases the aim pursued was the same: allowing them to freerly circulate, by removing barriers to trade. Yet, as we will see, the main rules of the market integration process were refined, by the Court of Justice mainly in its case law concerning food and beverages. Therefore, the purpose of this paragraph is to analyze the origin and the intimate connection of food law with the development of the leading principles of the EU internal market, as enshrined in the Treaties.

The legal shaping of the food sector, in fact, can be traced back to the creation of the "Common Market" which, together with the customs union were set as the building blocks of the Treaty of Rome[4], establishing the European Economic Community (EEC).

However, due to the absence of strong decision-making structures, the failure of the harmonisation efforts undertaken so far and the existence of non-tariff barriers, the ECC struggled to enforce a single market. Therefore, based on the 1985 White Paper Completing the Internal Market[5], the Single European Market Treaty was adopted, setting a deadline of 1992 for the single market to be up and running. In the end, it was launched on 1 January 1993[6]. It also introduced a new approach to harmonisation: a minimalist approach, providing for essential requirements rather than detailed and

[4]Treaty Establishing the European Economic Community. It was signed on 25 March 1957 by Belgium, France, Italy, Luxembourg, the Netherlands and West Germany and came into force on 1 January 1958.
[5] COM (35) Final, presented to the public by EC Commissioner Lord Cockfield on 15 June 1985
[6] EU glossary: Jargon SZ, 16 November 2010, available at http://www.bbc.com/news/world-europe-11769554

technical ones. Dealing with the definition of the internal market[7], the Court of Justice of European Communities[8] said that: "The Treaty, by establishing a common market and progressively approximating the economic policies of the Member States seeks to unite national markets in a single market having the characteristics of a domestic market[9]".

The so called 'four freedoms' lie at the core of the internal market: free movement of goods, persons, services and capital[10]. In particular, the free movement of goods is a fundamental principle under EU law: a product lawfully manufactured and/or marketed in one Member State is, in principle, entitled to be marketed in another EU Member State[11]. Nowadays, the EU internal market has made it easier to buy and sell products in 27 Member States, giving consumers a wider choice of products while being good for business.

Moreover, it must be underlined that around 75 % of intra-EU trade is in goods[12] and this is why the proper functioning of the market for goods is a crucial element "*for the current and future prosperity of the EU in a globalised economy*"[13].

---

[7] Article 26(2) TFEU '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.'

[8] With the entry into force of the Treaty of Lisbon in 2009, the court system obtained its current name Court of Justice of the European Union.

[9] Case 207/83 *Commission v UK* [1985] ECR 1202

[10] BARNARD C., *Competence review: The Internal Market*, 2013, p.3

[11] COUTRELIS N., WEBER I., *The Free Movement of Goods Principle Facing the Protection of National Public Health in the Absence of Harmonised Legislation: The Case of Processing Aids Used in the Manufacture of Foodstuffs*, in *European journal of Risk Regulation*, 2010, p. 263

[12] EUROPEAN COMMISSION, ENTERPRISE AND INDUSTRY DG, *Free movement of goods: Guide to the application of Treaty provisions governing the free movement of goods*, 2010, p.2

[13] Cf. Communication from the Commission — The internal market for goods: a cornerstone for Europe's competitiveness (COM (2007) 35 final). The free movement of goods represents the precondition for the functioning of the internal market and the first tool used for its creation. This is because, in the European market, even though Member States accept to lose sovereignty in order to ensure as far as possible the free movement of goods, services, persons and capitals, definitely their jeaolousy to regulate a certain sector, variates in relation to the freedom involved. In fact, while it is possible to have a system of regional integration were the free movement of goods is allowed, without guaranteeing the same freedom about persons and services (NAFTA could be an example), the opposite situation is not conceivable at all. This is the reason why EU internal market represents a model of regional integration.

The legal framework of the free movement of goods is now set in Part Three, Title II of the Treaty on the Functioning of the European Union[14]. The first provision of this Title, Article 28, deals with the two dimensions of the customs union: the first one[15] is the internal dimension, which covers the import and export of goods between Member States. In fact, it was established that the borders separating MSs had to be abolished over a transition period of twelve years[16], starting from the 1 January 1958, up to 1970. The second one is the external dimension, concerning trade with third countries[17], is linked with the idea of creating the same conditions all along the external border of the ECC for entry of goods from the world outside the ECC[18].

The second paragraph of Article 28 TFEU[19], in conjunction with Article 29 TFEU[20] extend the free market principle, which applies to products originating from EU, also to those goods coming from third countries. In fact, according to these provisions, "*if the import formalities have been complied with and any customs duties or charges having equivalent effect which are payable have been levied*", products coming from third countries "*shall be considered to be in free circulation in a Member State*" and therefore "*Article 30 and Chapter II of Title I shall apply*".

These provisions lay down the way of functioning of the external customs union, meaning that products coming from abroad, once duties and formalities have been complied with, shall be subject to the same treatment of products coming from EU.

[14] Hereinafter, TFUE

[15] Article 28 (ex Article 23 TEC) paragraph 1 "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…"

[16] This period was divided into three rounds, each of four years. The decision-making process was to be by unanimous vote during the first two periods and by majority vote in the last one.

[17] Article 28 (ex Article 23 TEC) par. 1 "…and the adoption of a common customs tariff in their relations with third countries."

[18] See note 1

[19]Article 28, paragraph 2 "The provisions of Article 30 and of Chapter 3 of this Title shall apply to products originating in Member States and to products coming from third countries which are in free circulation in Member States."

[20] Article 29 "Products coming from a third country shall be considered to be in free circulation in a Member State if the import formalities have been complied with and any customs duties or charges having equivalent effect which are payable have been levied in that Member State, and if they have not benefited from a total or partial drawback of such duties or charges."

The identity of custom duties and formalities is supposed to avoid a comparative disadvantage for a MS vis-à-vis other MSs[21]. Obviously, this mechanism can work only upon the condition that mutual trust[22] between them, exists. This assumption is true not only with regard to relations with third countries, but also when it comes to intra-EU trade.

Yet, finding the appropriate balance between the interests of the internal market, on the one hand, and national regulatory autonomy, on the other, is never easy[23]. In fact, the purpose of ensuring the free movement of goods has to face the fact that each Member State has its own national legal system[24], with its laws values and objectives, which could interfere with the free market purposes. Therefore, the ECC Treaty first, and the TFUE then, ordered the removal of all those kinds of national barriers (economic or technical ones) imposed on the import and export of goods, for the only reason of their crossing the borders between two Member States.

[21] For example: If there was no customs union, a Brazilian company would always choose, in order to export its product in the EU, the Member State whose custom duties are cheaper; the consequence would be that Brazilian companies would always opt for that MS, marketing its products there and creating for the competent authorities a huge burden in dealing with all products coming from Brazil.

[22] WRITE D., *The principle of mutual recognition within the EU´s Internal Market*, 21.3.2006, available at https://www.mpo.cz/zprava12653.html "The basic starting point of the principle of mutual recognition is the following idea: Member States acknowledge that even if products are manufactured in accordance with regulations, standards or procedures other than their own, these other norms guarantee a comparable level of safety and hence cannot be denied access to their market".

[23] PERISIN T., *Balancing Sovereignty with the Free Movement of Goods in the EU and the WTO - Non-Pecuniary Restrictions on the Free Movement of Goods* in *Croatian Yearbook of European Law & Policy*, Vol. 1, p. 109

[24] BROBERG M., VELDE M., *The embedding of food law into substantive EU law* in VAN DER MEULEN B., VAN DER MEULEN M. (eds.) *EU Food Law Handbook*, Wageningen, 2014, p. 212

1.1.1 Article 30 TFEU and the case law of the ECJ

The first step undertaken is the prohibition[25], between Member States, of customs duties on imports and exports (i.e. charges levied at the frontier of a state) and of charges having equivalent effect (for instance charges for storage and inspections on imported goods)[26]. During the preceding decades, in fact, several national legal instruments were used at the national borders on goods entering the state, providing for economic charges with different purposes: they may have a fiscal nature (being a source of income to the state budget), a protectionist nature (protecting the national economy against foreign competition), and a nature of negotiation (the countries can negotiate some customs facilities either bi-or multilaterally)[27].

Therefore, the absolute prohibition set out in Article 30 TFUE[28] has the aim to avoid discrimination vis-à-vis national and non-national producers, preventing the latter from suffering a comparative disadvantage, due to the higher costs they have to bear to export a certain product in that country.

This provision has been at the core of several rulings delivered by the European Court of Justice[29], which in its case law, concerning also food products and beverages, has been particularly engaged in clarifying the meaning of 'charges having equivalent effect". The concept of custom duties, in fact, has been much easier to be determined. They are taxes, with their own national names and usually *ad valorem*[30] (generally on the value of goods or upon the weight, dimensions, or some other criteria of the item), levied by reason of a good crossing the frontier.

[25] Set out in Article 25 TEC, now Article 30 TFEU
[26] See note 9
[27] PASAT O., *Customs Duties: Customs Tariff* in *Perspectives of Business Law Journal*, Vol. 2, Issue 1 (November 2013), p. 165
[28] Ex Article 12 EEC treaty
[29] At the beginning its name was the Court of Justice of the European Communities. Yet, after the entry into force of the Treaty of Lisbon, the European Community has now disappeared.
[30] DANIELE L., *Diritto del mercato unico europeo, cittadinanza, libertà di circolazione, concorrenza, aiuti di Stato***,** II edizione, Giuffrè, Milano, 2012, p.13

Yet it must be reminded that custom duties as such, have been at the core of one of the cornerstones of EU constitutional law[31], the *Van Gend and Loos* case[32], which was about Article 12[33] TEEC (now Article 30 TFEU). The Dutch government maintained that natural and legal persons had nothing to do with that article; it addressed only Member States and therefore they could not derive any right from it.

The Dutch court referred a preliminary ruling to the Court, which ruled that: "*The European Economic Community constitutes a new legal order of international law…the subjects of which comprise not only the Member States but also their nationals...community law not only imposes obligations on individuals but is also intended to confer upon them rights which become part of their legal heritage. These rights arise not only where they are expressly granted by the Treaty but also by reason of obligations which the Treaty imposes in a clearly defined way upon individuals as well as upon the Member States and upon the institutions of the Community*".[34] Therefore, by invoking the principle of direct effect of Article 12, the result was that every national law that increased duties was to be set aside by the ECC Treaty clause.

While determining the meaning and scope of custom duties is not so hard, the same cannot be said about "charges having equivalent effect". As usual, the case-law of the

[31] SHEBESTA H., *The foundations of the European Union*, in. VAN DER MEULEN B., VAN DER MEULEN M., *EU Food Law Handbook*, Wageningen, 2014, p.120

[32] Case 26/62, *NV Algemene Transport-en Expe ditie Onderneming Van Gend & Loos v. Nederlandse Administratie der belastinger*. It was about a Dutch company, which imported chemicals from Western Germany to the Netherlands. It was asked to pay an increase in a customs duty at the Dutch customs[32] but it refused on the ground that such duty ran contrary to the European Economic Community's prohibition[32] on inter-State import duties, set out in Article 12[32] TEEC (now Article 30 TFEU). The Dutch government, based on the protocol concluded between the Kingdom of Belgium, the Grand Duchy of Luxembourg and the Kingdom of the Netherlands at Brussels on 25 July 1958, ratified in the Netherlands by the Law of 16 December 1959, introduced a regrouping of existing duties. This included the increase in certain duties for goods that were brought into a different grouping. The Dutch government maintained that natural and legal persons had nothing to do with that article; it addressed only Member States and therefore they could not derive any right from it.

[33] It was a stand-still clause providing that "Member States shall refrain from introducing between themselves any new customs duties on imports or exports or any charges having equivalent effect, and from increasing those which they already apply in their trade with each other."

[34]Case 26/62, *NV Algemene Transport-en Expe ditie Onderneming Van Gend & Loos v. Nederlandse Administratie der belastinger*, p. 9

ECJ, in particular *Steinike*[35] and *Bauhuis*[36], has played a key role in clarifying this concept and in determining the characteristics which a national measure may have to fall within the scope of Article 30 TFEU.

In *Bauhuis*, in fact, the Court defined charges having equivalent effect as "*any pecuniary charge, whatever its designation and mode of application, which is imposed unilaterally on goods by reason of the fact that they cross a frontier and which is not a customs duty in the strict sense, constitutes a charge having equivalent effect*"[37].

To grasp this notion, several points must be underlined. First, the measure concerned shall have an economic nature, in order to be distinguished from measures adopted in violation of Articles 34 or 35 TFUE[38]. Secondly, it shall have a discriminatory nature, in fact, as the Court said: "*the essential characteristic of a charge having an effect equivalent to a customs duty, which distinguishes it from internal taxation, is that the first is imposed exclusively on the imported products whilst the second is imposed on both imported and domestic products*"[39]. This requirement excludes from the scope of Article 30 those national provisions that are imposed also on similar domestic products,

[35] Case 78/76, *Firma Steinike und Weanling, Hamburg v. Federal Republic of Germay, represented by the Bundesamt fur Ernährung und Forstwirtschaft (Federal Office for Food and Foresty), Steinike, 22 March 1977*, in Rac, p. 595, par. 28
This case was about Firma Steinike & Weinlig, a company which imported from Italy and third countries, citrus concentrates into the Federal Republic of Germany. When the imported product was processed, a demand was made on the plaintiff in the main action, by the competent federal agency for a contribution, intended to the "Fund for sales promotion in the German Agricultural and Food Industry and in German Forestry". The company challenged the legality of this contribution before a national court, claiming that Germany had infringed the prohibition of 'charges having equivalent effect to customs duties, under Articles 9 (1), 12 and 13 (2) of the EEC Treaty.
[36] Case 46/76, *W. J. G. Bauhuis v The Netherlands State*, 25 Genuary 1977. This case was about the payment, by the plaintiff in the main action of fees for veterinary and public health inspections, in accordance with a Dutch law, relating to livestock at the moment of import and export of bovine animals into and from The Netherlands. According to Mr Bauhuis, since such fees were levied in contravention of the Community provisions, which prohibited charges having an effect equivalent to customs duties on imports and exports, he asked for the total amount to be refunded.
[37] Bauhuis, see note 37, par. 9.
[38] Article 34 (ex Article 28 TEC) "Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States". Article 35 (ex Article 29 TEC) "Quantitative restrictions on exports, and all measures having equivalent effect, shall be prohibited between Member States."
[39] *Steinik*e, see note 36, par. 28

to which Article 110 TFEU[40] refers. This provision, in fact, supplements within the system of the Treaty, the prohibition of customs duties and charges having equivalent effect and it "*guarantees the complete neutrality of internal taxation as regards competition between domestic products and imported products*."[41]. Moreover, the charge shall be unilaterally imposed by the Member State concerned; economic charges provided by EU law, with the aim of enhancing intra-Eu trade, fall outside Article 30 TFEU.

For what concerns the scope of this provision, in *Steinike*, the Court said that "*the prohibition…is aimed at any tax demanded at the time of or by reason of importation and which, being imposed specifically on an imported product to the exclusion of a similar domestic product, results in the same restrictive consequences on the free movement of goods as a customs duty by altering the cost price of that product*"[42].

By adopting a substantive approach, rather than a formal one, the court emphasized the rationale of the prohibition set out in Article 30 TFEU: to avoid that Member States may circumvent this provision by adopting measures that, even though formally are not custom duties, substantially produce the same effect[43]. If these kinds of duties are in any case relevant with regard to both the internal and the external dimension of EU market, it is more with the second type of measures, discussed in the next paragraph, that food law is more involved.

[40]Article 110 (ex Article 90 TEC) paragraph 1: "No Member State shall impose, directly or indirectly, on the products of other Member States any internal taxation of any kind in excess of that imposed directly or indirectly on similar domestic products." Paragraph 2 "Furthermore, no Member State shall impose on the products of other Member States any internal taxation of such a nature as to afford indirect protection to other products."

[41] Case 168/78, 27 February 1980, *Commission of the European Communities v French Republic*, in Racc. p. 347

[42] *Steinike*, note 36, par. 28

[43] See note 21 Therefore, "where the conditions which distinguish a charge having an effect equivalent to a customs duty are fulfilled, the fact that it is applied at the stage of marketing or processing of the product subsequent to its crossing the frontier is irrelevant when the product is charged solely by reason of its crossing the frontier, which factor excludes the domestic product from similar taxation" Steinike, par. 29

1.1.2 Article 34 TFEU and the issue of 'measures having equivalent effect'

The second provision, addressing the free movement of goods, sets forth the ban of quantitative restrictions on trade (i.e. quotas or a total ban on imports) and measures having equivalent effect (rules on packaging, presentation and content of goods)[44].

This article plays a crucial role when it comes to the food sector, since for food products barriers to trade are mainly represented by technical standards, such as rules on weight, size, ingredients, mandatory labelling, shelf-life conditions, testing and certification procedures.

Dealing with the field of application of Article 34 TFEU[45], the concepts of "goods" and of "cross-border" trade shall be clarified. Regarding the first one, in its case-law[46] the Court has made evident that the range of goods covered is as wide as the range of goods in existence: "*by goods, within the meaning of the … Treaty, there must be understood products which can be valued in money and which are capable, as such, of forming the subject of commercial transactions*"[47].

[44] BARNARD C., *Competence review: The Internal Market*, 2013, p.13

[45]Article 34 TFEU (ex Article 28 TEC) "Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States" See European Commission, Enterprise and Industry DG, *Free movement of goods: Guide to the application of Treaty provisions governing the free movement of goods*, 2010 Even though Articles 34–36 TFEU lay down the groundwork for the general principle of the free movement of goods, they are not the only legal yardstick for measuring the compatibility of national measures with internal market rules. In fact, these provisions do not apply when the standards of a product are fully harmonised by EU law, because in this case any national measure must be assessed in the light of the harmonising provisions and not of those of the Treaty. Case C-309/02 *Radlberger Getränkegesellschaft and S. Spitz* [2004] ECR I-11763, par. 53 On the contrary, every time, in which harmonising legislation cannot be identified, Articles 34–36 TFEU can be relied on, representing a safety net, which guarantees that any obstacle to trade within the internal market can be scrutinised as to its compatibility with EU law

[46] In its rulings the Court of Justice has clarified on several occasions the proper designation of a particular product: i.e. (work of art) Case 7/78 *Thompso*n [1978] ECR 2247, (coins no longer in circulation and bank notes) Case C-358/93 *Bordessa and Others* [1995], ECR I-361, Case C-318/07 *Persche* [2009] ECR I-359, paragraph 29, (electricity) Case C-393/92 *Almelo v Energiebedrijf Ijsselmij* [1994] ECR I-1477, (natural gas) Case C-159/94 *Commission v France* [1997] ECR I-5815, (television signals are not goods) Case 155/73 *Sacchi* [1974] ECR 409.

[47] Case 7/68 *Commission v Italy*, 1968, ECR 42

Therfore, also food products are fully covered by this provision. Second, Article 34 TFEU (as well as Article 35 TFEU[48]) applies only as far as imports and exports between Member States are in place. This means that a cross-border element represents a prerequisite for evaluating a case under this provision, thereby purely national measures addressing only domestic goods, fall outside the scope of Articles 34–36 TFEU[49].

While Articles 30 and 34 have in common the fact that they are both about potential national laws restricting the market, many differences exist. First, the measures addressed by the provision at stake are not economic pecuniary charges, differently from those ones which fall under Article 30 TFEU. These measures, in fact, are included within the broader concept of "non-tariff barriers to trade"[50] (NTBs) which, as already said, is of crucial importance for the European and intenational markets of food products .

They are defined as "*any measure (public or private) that causes internationally traded goods or services, or resources devoted to the production of these goods and services, to be allocated in such a way as to reduce potential real-world income*"[51]. Formal quantitative restrictions have been quite easily defined by the Court, as measures which amount to a total or partial restraint on imports or goods in transit[52]. When they are in place, only a certain amount (quota or percentage) of goods is allowed to be imported in a given year[53].

---

[48] Article 35 TFEU (ex Article 29 TEC) "Quantitative restrictions on exports, and all measures having equivalent effect, shall be prohibited between Member States"

[49] European Commission, Enterprise and Industry DG, *Free movement of goods: Guide to the application of Treaty provisions governing the free movement of goods*, 2010, p. 10

[50]TERCHETE J.P., *Non-tariff barriers to trade*, in *Max Planck Encyclopedia of Public International Law*, 2014, p.8 On the World Trade Organization level, the Table of Contents of the 2003 Inventory of Non-Tariff Measures (WTO Doc TN/MA/S/5/Rev. 1) differentiates between six types of NTBs. For what concerned the provision at stake, two of them (technical barriers to trade, sanitary and phytosanitary standards) may fall within the meaning of "measures having equivalent effect".

[51]BALDWIN R. E., *Non-tariff Distortions of International Trade*, , in *Journal of International Economics*, vol. 2, fasc. 3, 1970, p.5

[52] Case 2/73 *Geddo* [1973] ECR 865

[53] See note 54 Therefore, once the imports reach the quota limit, it is no longer possible for that product to be imported, until a new year has begun

While the concept of quantitative restrictions is crystal clear, that of "measures having equivalent effect" was disputed for a long time in academic writings[54]. In fact, this type of measures albeit not taking the form of a straight limitation of a quantity, practically speaking have the same result[55]. For decades the ECJ has been trying to determine the precise meaning and scope of this provision, not a simple task at all[56].

Yet, its the case-law on food standards have been pivotal to face this issue, since the main judjments delivered by the Court, concerned bevareges and the related technical standards imposed by a certain Member State preventing foreign food products to enter its market. There are different possibilities to interpret this concept, as one can stress more the word "equivalent" or the word "effect"[57]and the approach adopted by the ECJ was explained in *Dassonville*[58].

The case concerned parallel imports on Scotch whisky in Belgium[59]. Mr. Dassonville and his son used to buy this whisky in France (where it was cheaper) with the aim of re-importing it to Belgium. The national provision at stake was a Belgian provision requiring, in order for such products to be imported, a certificate of origin from the British authority. The same requirement was not imposed by France, therefore the Dassonvilles, who bought Scotch whisky from France, and not directly from the UK, created their own certificate to comply with the Belgian standard. When Belgian

[54]RINZE J., *Free Movement of Goods: Art, 30 EEC-Treaty and the Cassis-de-Dijon Case-Law in Bracton Law Journal*, Vol. 25, p. 67 This was because, as it became clear at the time when the EEC-Treaty was negotiated, Member States used to replace protective quantitative restrictions by technical rules which, at first sight, applied equally to domestic and imported products, although in in practical terms, having a disguised protective effect.

[55] An example was a Dutch law adopted in the 1950s, that in order to limit the importation of wheat, prescribed bakers to bake bread only with a certain percentage of Dutch-grown wheat.

[56] PERISIN T., *Balancing Sovereignty with the Free Movement of Goods in the EU and the WTO - Non-Pecuniary Restrictions on the Free Movement of Goods* in *Croatian Yearbook of European Law & Policy*, Vol. 1, p. 110; She explains that this definition is not easy to be given especially since the many factual and legal circumstances at the core of this article may change so fast that what was valid in the past can no longer be accepted

[57] See note 65 They can be defined in light of their purpose (i.e. to protect national production from imports), in light of their effects (i.e. to favour domestic products) or in a broader manner as meaning any kind of measure restricting the freedom to import products from a Member State to another one.

[58] Case 8/74 *Dassonville*, [1974] ECR 837

[59] MEULEN B., *Food law: development, crisis and transition*, in VAN DER MEULEN B., VAN DER MEULEN M. (eds.) *EU Food Law Handbook*, Wageningen, 2014 p. 203

authorities found out this practice, charged them with fraud. In *Dassonville,* an heroic[60] "umbrella definition" was given by the Court, which stated that: "*All trading rules enacted by Member States which are capable of hindering, directly or indirectly, actually or potentially, intra Community trade are to be considered as measures having an effect equivalent to quantitative restrictions*."[61].

In the middle of the academic debate concerning this issue, the European Commission has made clear its view in the Directive 70/50/EEC[62]. Article 2 of the Directive covered "distinctly applicable"[63] measures which could hinder imports, while Article 3 prescribed that it "*also covers measures governing the marketing of products... which are equally applicable to domestic and imported products, where the restrictive effect of such measures on the free movement of goods exceeds the effects intrinsic to trade rules*". On the other hand, the broader view in the academic writing was strongly convinced that not only "distinctly applicable" measures but any kind of "national

[60] For a general overview on the reasons behind the heroic character see WEILER J. H.H., *Epilogue: Towards a Common Law of International Trade*, in *THE EU, THE WTO, AND THE NAFTA-TOWARDS A COMMON LAW OF INTERNATIONAL TRADE?*, Oxford University Press, Oxford, 2000 and GREEN N., HARTLEY T., USHER J. A., *The legal foundations of the Single European Market*, 1991, p. 52 and OLIVER P., *Free movement of goods in the E.E.C.: under Articles 30 to 36 of the Rome Treaty*, 2 e.d., 1988. To understand the "heroic" character of such definition, they give a brief description on the academic background existing at the time of this ruling. Until 1974 the dispute on the meaning of "measures having equivalent effect" was between three main schools of thought a wide definition, an intermediate and a narrow opinion. According to the last one, only "distinctly applicable" measures could fall within the scope of Article 34. The argument was based on the assumption that these measures can be deemed to be equivalent to quantitative restriction only as far they pursue the same aim, (i.e. to be protective) and therefore to discriminate.

[61] Case 8/74 *Dassonville*, [1974] ECR 837, par. 5

[62] Directive 70/50/EEC on the abolition of measures which have an effect equivalent to quantitative restrictions on imports and are not covered by other provisions adopted in pursuance of the EEC Treaty (OJ L 13, 19.1.1970, p. 29

[63] On the issue see, inter alia, PERISIN T., *Balancing Sovereignty with the Free Movement of Goods in the EU and the WTO - Non-Pecuniary Restrictions on the Free Movement of Goods* in *Croatian Yearbook of European Law & Policy*, Vol. 1, who defines distinctly applicable measures as" a measure that is applied differently to goods, persons, services or capital depending on their Member State of origin, thus amounting to discrimination. Indistinctly applicable measures in their face do not prescribe differential treatment, but they may impose either an additional or an equal burden. In the former case, their effect is discriminatory (indirect discrimination) even though there need be no discriminatory or protectionist motive, while in the latter case such measures can be regarded as non-discriminatory."

provision able to restrict the free import of goods"[64] in the context of intra-EU trade, should be banned.

This was the approach that in 1974, the Court adopted in *Dassonville*, where it decided to take a more active role in enhancing the European market by delivering "the first case that went beyond the conservative view of a liberal trade regime"[65]. In fact, even though in its reasoning, it didn't address the issue of discrimination directly, decided that "..*the requirement by a Member State of a certificate of authenticity which is less easily obtainable by importers of an authentic product which has been put into free circulation in a regular manner in another Member State than by importers of the same product coming directly from the country of origin constitutes a measure having an effect equivalent to a quantitative restriction as prohibited by the Treaty*"[66].

The Court recognized that a situation of *de facto* discrimination was at stake: even if the national measure did not prevent non-direct importers from importing Scotch whisky in Belgium, *de facto*, they were treated less favorably than direct ones, since "*only direct importers were really in a position to satisfy [the Belgian requirement] without facing serious difficulties*"[67].

A shift from the "discriminatory approach"[68] towards the "market access"[69] approach was done. If the national measure is able to hinder intra-EU trade, it is presumptively contrary to Article 34, unless the state can show that it is justified[70].

---

[64] See note 65
[65] See note 72
[66] Case 8/74 *Dassonville*, [1974] ECR 837, par. 9
[67] Ibid., par. 8
[68] See Opinion of Advocate General M. P. MADURO, delivered on 30 March 2006, Joined cases C-158/04 and C-159/04**.**, *Alfa Vita Vassilopoulos and Carrefour Marinopoulos v Elliniko Dimosio and Nomarchiaki Aftodioikisi Ioanninon*.
[69]See Opinion of Advocate General Jacobs, devilered on 24 November 1994, C-412/93 *Société d'Importation Edouard Leclerc-Siplec v TF1 Publicité SA and M6 Publicité SA.* Such approach does not care about the different treatment of national and non-national goods, but it looks at the national measure solely from the perspective of the out-of-state trader.
[70] BERNANRD C., *Competence review: The Internal Market*, 2013, p.14

The reasoning followed in *Dassonville* became clearer in another ruling, delivered five years later, known as *Cassis de Dijon*[71].

Again, this case was a perfectly clear example of how the setting of a technical standard, even by indistinctly applicable measures, may obstruct cross-border trade[72]. At the same time, it represents a major step forward from *Dassonville* form two main reasons. First, the Court made clear the scope of the principle of mutual recognition: products lawfully[73] produced and marketed in one Member State, may not be kept out from another Member State, on the ground that they do not comply with national rules[74]. In fact, while recognizing that "*in the absence of common rules it is for the Member States to regulate all matters relating to the production and marketing of alcohol and alcoholic beverages on their own territory*"[75], concluded that "there is no valid reason why, provided that they have been lawfully produced and marketed in one of the Member States, alcoholic beverages should not be introduced into any other Member State"[76].

Therefore, "*its principle of mutual recognition shifted the burden of proof to the traders' advantage*"[77], meaning that it was up to the State to justify the restriction and not for the importers to prove the restrictive nature of the measure. This ruling, in fact, is considered a pillar for the well-functioning of the EU market and a cornerstone for

[71] Case-120/78 *Rewe-Zentrale AG v Bundesmonopolverwaltung fur Branntwein, (Cassis de Dijon*) [1979] ECR 649 In the case, a German chain of supermarket wanted to import the French fruit liquor Cassis De Dijon, containing a low amount of alcohol. The national provision at stake was a German law, providing "that only potable spirits having a wine-spirit content of at least 25 % may be marketed in that country", and Cassis did not fulfill such requirement because it contains only from 15 to 20% wine-spirit by volume

[72] WEATHERILL S., *Free Movement of Goods* in *International and Comparative Law Quarterly*, Vol. 50, Issue 1, January 2001, p.158

[73]There was academic debate about the meaning of "lawfully produced in a M.S. According to RINZE J., "Products have neither to be lawfully produced nor do they have to be produced in a Member State to apply the Cassis de Dijon principles". See RINZE J., *Free Movement of Goods: Art, 30 EEC-Treaty and the Cassis-de-Dijon Case-Law in Bracton Law Journal,* Vol. 25, p. 67-76

[74] VAN DER MEULEN B., *Food law: development, crisis and transition*, in VAN DER MEULEN B. (ed.) *EU Food Law Handbook,* Wageningen, 2014 p. 204

[75]*Cassis de Dijon*, [1979] ECR 649, par 8.

[76]Ibid. par 14

[77] PERISIN T., *Balancing Sovereignty with the Free Movement of Goods in the EU and the WTO - Non-Pecuniary Restrictions on the Free Movement of Goods* in *Croatian Yearbook of European Law & Policy,* Vol. 1, p. 117

food law, since it provides that a product is consumer-friendly in a Member State as far as it is good for consumers across the Union.

Thanks to these two leading cases, it could be concluded that Article 34 TFEU applies not only to "distinctly applicable measures", but also to "indistinctly applicable"[78] ones. Soon after the Cassis ruling, the Court had to face a flood of cases[79], brought by traders, showing with an unambiguous evidence, that Article 34 TFEU used to be "*pushed beyond its function in eliminating impediments to the integration of the markets of the Member States towards a general charter for attacking any inhibition on economic freedom*"[80].

In *Keck*[81], in fact, "*in view of the increasing tendency of traders to invoke [Article 34] as a means of challenging any rules whose effect is to limit their commercial freedom even where such rules are not aimed at products from other Member States*", the Court considered "*necessary to re-examine and clarify its case-law on the matter*"[82]. After recalling *Cassis* in fact, the Court stated that "*contrary to what has previously been decided, the application to products from other Member States of national provisions restricting or prohibiting certain selling arrangements is not such as to hinder directly*

[78] Case C-110/05 Commission v Italy [2009] ECR I-519, par. 35 As already said, this term is used for those national provisions which, while in law seem to apply equally to national and non-national products, in practice are more burdensome for the latter. The difference in treatment derives from the fact that only the imported goods are required. The difference in treatment derives from the fact that only the imported goods are required to comply with two sets of rules provided by both the country of origin and the country of destination of the product. See EUROPEAN COMMISSION, ENTERPRISE AND INDUSTRY DG, *Free movement of goods: Guide to the application of Treaty provisions governing the free movement of goods*, 2010, p. 12

[79] A famous example was the "Sunday trading" case, Case 145/88 Torfaen BC v. B & Q plc [1989] E.C.R. 765

[80] WEATHERILL S., *Free Movement of Goods* in *International and Comparative Law Quarterly*, Vol. 50, Issue 1, January 2001, p.160, MADURO P. M., *Harmony and Dissonance in Free Movement* in, Services and free movement in EU law, Oxford, 2002 As the Advocate General Maduro noted, this overloading of cases could also amount to a threat to the Court's legitimacy the economic analysis of market laws entails an operation of balancing between public and commercial interests which should remain in the discretion of Member States.

[81] Cases C-267 and C-268/91 *Keck and Mithouard* [1993] E.C.R. 1-6097 The case was about a French provision prohibiting the so called "re-sale at a loss". Criminal proceedings were brought against Mrs. Keck and Mithouard, who used to resale products, in an unaltered state, at prices lower than their actual purchase price.

[82] Ibid par. 14 Yet, while *Dassonville* and *Cassis* were about "product standards" (i.e. how products are produced), *Keck* was about "selling arrangements" (i.e. how products are marketed and sold)

or indirectly, actually or potentially, trade between Member States within the meaning of the Dassonville judgment so long as those provisions apply to all relevant traders operating within the national territory and so long as they affect in the same manner, in law and in fact, the marketing of domestic products and of those from other Member States"[83]. Should these conditions be fulfilled, the national rule concerned would "*not (be) by nature such as to prevent their access to the market or to impede access any more than it impedes the access of domestic products*"[84].

By adopting a discriminatory approach, the Court was able to withdraw a whole category of indistinctly applicable measures from the scope of Article 34 TFEU[85]. While these were the arguments given to emphasize the first step further which Cassis de Dijon made in respect of *Dassoville*, with the issue of "justifications" *we can move to the second one: the introduction of the concept of "mandatory requirements*".

[83] Ibid. par. 16
[84] Ibid par. 17
[85] The same result was reached in two other ways: on the one hand, *in Krantz* the formula "too uncertain and indirect" was developed to correct the inadequacies of the Keck case-law C-69/88 *H Krantz GmbH & Co. v Ontvanger der Directe Belastingen and Netherlands State* [19901 ECR 1-0583, par. 11 "too uncertain and indirect to warrant the conclusion that a national provision authorizing such seizure is liable to hinder trade between Member States*".* On the other hand several justifications were added to those set forth in Article 36 TFEU

1.1.3 The protection of food safety and human health as a limit to the free movement of goods. Justifications: Article 36 TFEU and the 'Cassis clause'

In every system that strives to achieve free trade, it is necessary to balance this aim with the protection of other values[86]. "*A value is an enduring belief that a specific mode of conduct is socially preferable relative to an opposite or converse mode of conduct*"[87]. As Fekete points out, value orientation guides human activities from the easiest infrastructures to the most important organizations and institutions, in order to safeguard general accepted values such as labour, environment, human health and the connected food safety[88].

Each society possesses more than one value and therefore it is not unlikely that, for instance, enanching the protection of public health through rigid food standards may, at the same time, conflict with the need of freedom that commercial transational transactions require. Such balancing has not only economic implications for trade and competition among companies, but also for national regulatory sovereignty and constitutionalism[89].

The presumption of equivalence or mutual recognition of standards, affirmed in the *Dassonville* case, in fact, is not an absolute one. It means that, while under Article 30 TFEU no derogation is allowed, Article 34 TFEU shall be read in conjunction with Article 36 TFEU[90], which lists possible exceptions to the free movement of goods. National laws impeding cross-border trade can be justified not only under the express derogations laid down in the Treaty but also under one of the so called 'mandatory

[86] See note 91
[87] ROKEACH M., *The nature of human values*, New York, 1973, p.10
[88] FEKETE J., *Introductory Note for a Postmodern Value Agenda*, in FEKETE J. (ed.*) Life after postmodernism:essays on value and culture*, 1987, p.5
[89]MADURO M. P., *The Constitution of the Global Market*, in *Regional ang global regulation of international trade*, Hart Publishing, Oxford, 2002
[90]Article 36 TFEU (ex Article 30 TEC) "The provisions of Articles 34 and 35 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States".

requirements'[91]. A preliminary remark shall be done. Usually, if a certain sector is not harmonized at the EU level Member States retain discretion in setting their own level of protection of public goods. On the other hand, if the EU legislator has exhaustively regulated a certain matter, the Member State are normally barred from introducing or maintaining contrasting national measures. Therefore, Article 36 TFEU as well as the Cassis clause, cannot be relied on to justify deviations from harmonized EU legislation[92].

This second type of derogation (public interest requirements or objective justifications) has been developed through the case-law of the ECJ and it was first enshrined in the *Cassis* case. Here the Court stated that "*obstacles to movement within the Community resulting from disparities between the national laws relating to the marketing of the products… must be accepted in so far as those provisions may be 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 transactions and the defense of the consumer*"[93].

In the present case, in fact, the German authorities, while acknowledging that the minimum content of alcohol amounted to a restriction on trade, sought to justify it on the basis that beverages with too little alcohol posed several risks[94], "*adducing considerations relating on the one hand, to the protection of public health and on the other, to the protection of the consumer against unfair commercial practices*"[95].

The Court was not persuaded by the arguments put forward by Germany and concluded that "*the principle effect of requirements of this nature is to promote alcoholic*

[91] BERNANRD C., *Competence review: The Internal Market*, 2013, p. 9
[92] Case C-473/98 *Toolex* [2000] ECR I-5681; Case 5/77 *Tedeschi v Denkavit* [1977] ECR 1555
[93]Case-120/78 *Rewe-Zentrale AG v Bundesmonopolverwaltung fur Branntwein*, (*Cassis de Dijon*) [1979] ECR 649, par. 8
[94] MEULEN B., *Food law: development, crisis and transition*, in VAN DER MEULEN B., VAN DER MEULEN M. (eds.) *EU Food Law Handbook*, Wageningen, 2014 p. 203
[95]*Cassis de Dijon*, [1979] ECR 649, par. 10 and 12. The first argument was based on the assumption that "such products may more easily induce a tolerance towards alcohol than more highly alcoholic beverages", while the second one relied on the fact that "the lowering of the alcohol content secures a competitive advantage in relation to beverages with a higher alcohol content, since alcohol constitutes by far the most expensive constituent of beverages by reason of the high rate of tax to which it is subject."

beverages having a high alcohol content by excluding from the national market products of other Member States"[96]. In fact, while in principle consumer protection amounts to a public good worthy to be pursued, in the present case the national measure didn't meet the standard of reasonableness[97].

The "rule of reason" imposes on both treaty derogations and mandatory requirements, the requirements of proportionality and necessity of the measure concerned. The proportionality test is satisfied when the measure "*is appropriate for securing the attainment of that objective and does not go beyond what is necessary in order to attain it*"[98]. Necessity moreover, means that the restriction must "*be confined to what is actually necessary to ensure the safeguarding of...the objective thus pursued, which could not have been attained by measures which are less restrictive of intra-Community trade*"[99].

The proportionality test in several cases resulted in the conclusion that the measure at stake was not justifiable, making evident that proportionality is "*a matter in which the ECJ can exercise a great deal of discretion*"[100]. In addition, the fundamental requirement that both measures justifiable under Article 36 TFEU or under the Cassis clause must have is that they shall pursue non-economic[101] values only. The second paragraph of Article 36, in fact, states that: "*Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on*

[96]*Cassis de Dijon*, [1979] ECR 649, par. 14

[97] The public health argument was dismissed on the ground that "the consumer can obtain on the market an extremely wide range of weakly or moderately alcoholic products" (par. 11), while the aim to protect consumers was dismissed on the ground that "it is a simple matter to ensure that suitable information is conveyed to the purchaser by requiring the display of an indication of origin and of the alcohol content on the packaging of products" (par. 13)

[98] Case C-390/99 *Canal Satélite Digital* [2002] ECR I-607, par. 33. See also, inter alia, Case C-76/90 *Säger* [1991] ECR I-4221, par. 15; Joined Cases C-369/96 and C-376/96 *Arblade and Others* [1999] ECR I-8453, par. 35; and *Corsten*, par. 39, Case C-254/05 *Commission v Belgium* [2007] ECR I-4269, par. 33, Case C-286/07 *Commission v Luxembourg*, par. 36

[99]Case C-319/05 *Commission v Germany* (Garlic) [2007] ECR I-9811, par. 87. See also, inter alia, *Sandoz*, par. 18, *Van Bennekom*, par. 39; Case C-192/01 *Commission v Denmark* [2003] ECR I-9693, par. 45; and Case C-24/00 *Commission v France* [2004] ECR I-1277, par. 52

[100] GORMLEY L.W., *Free Movement of Goods and Their Use - What is the Use of It* in *Fordham International Law Journal*, Vol. 33, Issue 6, June 2010, p. 1593

[101] See, inter alia, Case C-120/95 *Decker* [1998] ECR I-1831; Case 72/83 *Campus Oil* [1984] ECR 2727

trade between Member States." As the Court said, the rationale of this sentence "*is to prevent restrictions on trade based on the grounds mentioned in the first sentence, from being diverted from their proper purpose and used in such a way as to create discrimination in respect of goods originating in other Member States or indirectly to protect certain national products"*[102].

Therefore, Member States cannot seek to justify protectionist behaviours by relying on these exceptions. This "ordo-liberal dimension" of the European Union, thereby market issues have always to be balanced with social welfare and non-trade values, is confirmed also by Part I, Title II TFEU which sets forth "Provisions having general application". Articles 8-14 TFEU require, in fact, non-economic interests (such as employment, environment, consumer protection, animal welfare) to be integrated in the definition and implementation of all EU policies and activities.

Albeit these similarities, "*the issue of whether or not to assimilate the case-law-based justifications [to the treaty-based ones] is one on which the overwhelming majority of authors are agreed: this is not something which should happen*"[103].

First, the general interest exceptions enlisted in Article 36 TFEU (i.e. 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) are a static and exhaustive list, which the ECJ has always interpreted narrowly. On the other hand, case-law derogations are a dynamic and open list (i.e. the effectiveness of fiscal control, the protection of public health, the fairness of trade relations, consumers' and environmental protection), created by the ECJ in order to grasp the economic and social changes of the market.

[102] Case 34/79 *Henn and Darby* [1979] ECR 3795, par. 21. See also joined Cases C-1/90 and C-176/90 *Aragonesa de Publicidad Exterior and Publivía* [1991] ECR I-4151, par 20.
[103]GORMLEY L.W., *Free Movement of Goods and Their Use - What is the Use of It* in *Fordham International Law Journal*, Vol. 33, Issue 6, June 2010, p. 1592

Second, while treaty-based derogations can be relied on to justify discriminatory as well as indistinctly applicable measures, grounds other than those covered by Article 36 TFEU may not be used to justify distinctly applicable measures[104], otherwise Member States would have too much discretion.

Confusion between these two types of limitations was created with regard to the protection of public health. It was caused by the inclusion of such public interest among mandatory requirement in the *Cassis* case[105].

Yet, through its case-law[106] the Court clarified that the protection of public health falls under Article 36 TFUE and it's this general interest that makes EU food law coming to the fore. Food safety, in particular, falls under the public health exception and therefore represents a lawful objective to be pursued at the supernational level as well as at the national one. European food law, in particular, has developed in several stages. As it will be discussed in the next paragraphs, from the Treaty of Rome up to the 1990s, it was mainly directed towards the creation of a European free market of food.

Yet, Due to the consumers' trauma and public concern that several food safety crisis created in the 1990', the market-oriented approach has been replaced by a new consumer-oriented policy, focused on safety and precautionary. The EU institutions, in fact, decided to step in and to undertake a positive action in order to regulate the food sector, on the one hand by limiting Member States' discretion in addressing food issues and on the other, by placing consumer protection at the core of EU food policy.

[104] EUROPEAN COMMISSION, ENTERPRISE AND INDUSTRY DG, *Free movement of goods: Guide to the application of Treaty provisions governing the free movement of goods*, 2010, p. 28
[105]Cassis de Dijon, [1979] ECR 649, par. 8
[106]See *Aragonesa de Publicidad Exterior SA v. Departmento de Sanidad y Seguridad Social de la Generaliteit de Catalufia*, Joined Cases C-1 & 176/90, [1991] E.C.R. 1-4151, par. 9-13.

1.2. The second dimension of food law: The birth of European Food Law

1.2.1 The market-oriented approach to food law: from vertical directives to horizontal secondary law

As the EU's directorate general for Enterprise and Industry stressed out, since the food sector is the largest production sector in the European Union, the food industry happens to be in the top three of most regulated industrial sectors[107].

As already said, the free movement of food, differently from other goods, had to face several obstacles in order to be fully achieved[108]. Two were the main reasons: the challenging task of setting of a common notion of "food quality" all around Europe, as well as the lack of specific provisions in the Treaties[109]. Regarding the first one, determining the meaning of quality when it comes to foodstuff, is a competence of both EU institutions and Member States[110]. The second reason lies in the fact that, while the Treaty of Rome provided for specific rules concerning agriculture and fisheries, the free movement of food in general was subject to the Treaty provisions on the free movement of goods.

Owing to the peculiarities of the agricultural sector, in fact, the inclusion of the common agricultural policy (CAP) under the EEC was not an easy task. Created in 1962, it is one of the oldest polices of the European Union[111]. Today, the main objectives of the CAP are "*to provide a stable, sustainably-produced supply of safe food at affordable prices for Europeans, while also ensuring a decent standard of living for farmers and agricultural workers*"[112]. The legal fundament of CAP is set in Part

---

[107]VAN DER MEULEN B., *The food sector and its law*, in VAN DER MEULEN B., VAN DER MEULEN M (eds.) *European food law handbook*, Wageningen, 2014 p.39

[108] COSTATO L., *Il diritto alimentare: modello dell'unificazione europea* in *Rivista di Diritto Alimentare*, 2009, fasc. 3, p. 1

[109] ACCONCI P., *Riflessioni sull'accezione di qualità dei prodotti agroalimentari rilevante nel diritto dell'Unione europea*, in *Studi sull'integrazione europea*, 2016, p. 265-287

[110] ZILLER J., SALA-CHIRI G., *The EU multilevel food safety System in the Context of the Principle of Conferral*, in LUPONE A., RICCI C., SANTINI A. (eds.) *The right to safe food towards a global governance*, Torino 2013, p. 229 e ss.

[111] Major reforms shaped the CAP in 1992, 2003 and 2013, adapting the policy to a changing world.

[112] DG for Agricultural and rural development, *The history of the common agricultural policy*, available at https://ec.europa.eu/agriculture/cap-overview/history_en

III, Title III TFEU which unless otherwise provided, subjects agricultural products to the rules laid down for the establishment and functioning of the internal market[113]. In this regard, it shall be noted that the quantity and quality of EU secondary law concerning agriculture acted as a unifying force in the European integration process[114].

When it comes to food products more in general, the basic objectives of the Single Market for foodstuffs were laid down in the Communication on Community Food Legislation in November 1985[115]. The Commission made it clear that harmonization in the field of food products should be aimed at: the protection of public health, ensuring free and fair trade, guaranteeing consumer information, and providing necessary public controls[116]. Mutual recognition[117] should apply and the principle of proportionality when restricting the free movement of food should be respected. Such general approach was meant to overcome the difficulties encountered in the past, due to the so called "vertical directives"[118].

The market-oriented phase of the European food market, in fact, can be subdivided in two stages: the first one characterised by vertical directives, the second one by

[113]Article 38 TFEU (ex Article 32 TEC) par. 2 "Save as otherwise provided in Articles 39 to 44, the rules laid down for the establishment and functioning of the internal market shall apply to agricultural products"

[114] For a more detailed analysis of the historical evolution of CAP, see COSTATO L., *La controriforma della PAC* in *Rivista di diritto agrario,* 2010, fasc. 2, p. 369-378, COSTATO L., *La Pac [Politica agricola comune] riformata, ovvero la rinuncia a una politica attiva* in *Rivista di diritto agrario*, 2012, fasc. 2, p. 393-404, COSTATO L., *Riforma della PAC e rifornimento dei mercati mondiali di prodotti agricoli alimentari* in *Diritto e giurisprudenza agraria, alimentare e dell'ambiente,* 2011, fasc. 2, pt.1, p. 87-91,

[115] COM (85) 603 final

[116] KAYAERT G., *The European Market for Food Products* in *Food and Drug Law Journal*, Vol. 51, Issue 4, 1996, p. 720

[117] "In the absence of harmonised Community rules, the Member State have the power to lay down, in respect of their own production, rules governing the manufacture, composition, packaging and presentation of foodstuffs. On the other hand, they are required to admit to their territory foodstuffs lawfully produced and marketed in another Member State. The importation and marketing of foodstuffs lawfully produced and marketed in another Member State may be restricted, in the absence of harmonised rules at Community level, only where such a measure: * can be demonstrated to be necessary in order to satisfy mandatory requirements (public health, protection of consumers, fairness of commercial transactions, environmental protection); * is proportionate to the desired objective; and * is the means of achieving that objective which least hinders trade."

[118] E.g. Directive 73/241/EEC, 1973 on cocoa and chocolate products; Directive 73/437/EEC, 1978 on sugar; Directive 74/409/EEC, 1974 on honey.

horizontal secondary law[119]. As already explained, the original goal of the EEC was the creation of a common market. Although it seemed attractive, countless national provisions, providing for different standards for products, have impeded the free movement of goods for a long time. As already said, this happened mainly in the food sector, were technical standards on food staff (weight, size, packaging, ingredients, mandatory labelling, shelf-life conditions, testing and certification procedure etc.) were often issue of disputes. To overcome such obstacles, positive harmonization was thought to be the key. The creation of similar standards all over Europe was achieved thanks to "vertical directives"[120], setting compositional requirements for several food products.

Yet, such approach revealed its deficiencies soon. First, it was too time-consuming and unfeasible to set detailed standards for each product, since there are too many food products to be dealt with. Second, unanimity for adopting new legislation was required[121] and it was not an easy task to find an agreement on such sensitive issues.

It was mainly the case-law[122] of the ECJ that was able to overcome the impasse and *Cassis* represented a turning point in this regard. In the absence of harmonization, in fact, was the principle of mutual trust, as designed by the Court in that case, the tool to ensure the freedom of movement of food. The application of such principle, which is based on the presumption of equivalence of different national legal systems, required that food products lawfully produced in a Member State shall in principle (unless a general interest exception is at stake), be able to freely circulate within the EU market.

---

[119] VAN DER MEULEN B., *Food law: development, crisis and transition* in VAN DER MEULEN B., VAN DER MEULEN M. (eds.) *European food law handbook*, Wageningen, 2014, p. 219

[120] Ibid.

[121] Art 100 of the Rome Treaty, now Art 115 TFUE "Without prejudice to Article 114, the Council shall, acting unanimously in accordance with a special legislative procedure and after consulting the European Parliament and the Economic and Social Committee, issue directives for the approximation of such laws, regulations or administrative provisions of the Member States as directly affect the establishment or functioning of the internal market"

[122] See, inter alia Case 178/84 *Commission v. Germany*, 12 March 1987, (Reinheitsgebot), Joined cases C-46/93 and C-48/93 *Brasserie du Pècheur SA v Bundesrepublik Deutschland and The Queen v Secretary of State for Transport*, 5 March 1996.

Therefore, the concept of negative harmonization as opposite to the one of positive harmonization came to the fore and here we come to the second phase of the market-oriented dimension of the European food market, characterized by a shift from vertical directives, to horizontal legislation[123]. It means that EU secondary law was based on a minimalist approach, providing for "general rules addressing common aspects for all food staff, or at least for as many foodstuffs as possible"[124]. Regulatory interventions by EU institutions kept on growing during the years, in order to grasp and legally shape economic and social changes such as industrialization, delocalization, opening of the market towards third countries, the increasing of the pollution level and the diffusion of epidemics caused by food products[125], in particular the so-called BSE[126] crisis.

1.2.2 The BSE crisis in the 1990' and the consumer-oriented approach to food law

As underlined in the previus parapgraphs, at the beginning food products were not addressed by specific rules different for those concerning products in general and attention on food safety issues was not paid by EU until the 1980'. Yet, it was only after the consumer trauma related to the mad cow disease that it is possible to talk about the full implementation of the second dimension of food law: the development of EU food law. Until the outbreak of this epidemic, in fact, many of the European rules concerning food safety were created and developed on an "ad hoc" basis or through the case-law of the ECJ.

"*The BSE crisis, however, clearly demonstrated that where important political interests are at stake, this ad hoc approach is not sufficient to guarantee an effective*

[123] E.g. Directive 2000/13 the "Labelling Directive" (now replaced by Regulation 1169/2011), Directive 93/43 the "Hygiene Directive" (now replaced by Regulations 852-854/2004)
[124]VAN DER MEULEN B., *Food law: development, crisis and transition* in VAN DER MEULEN B., VAN DER MEULEN M. (eds.) *European food law handbook*, Wageningen, 2014, p.205
[125]ACCONCI P., *Riflessioni sull'accezione di qualità dei prodotti agroalimentari rilevante nel diritto dell'Unione europea*, in *Studi sull'integrazione europea*, 2016, p. 272
[126] Bovine spongiform encephalopathy (BSE) is a new degenerative brain disease affecting cattle which occurred for the first time in the United Kingdom in 1985.

and legitimate food safety policy and decision-making free from manipulation and capture"[127]. Moreover, it was also an important lesson for the Commission capabilities in the field of risk management and regulation, which at that time, were not evaluated positively.[128] An overall analysis of the time line of events with regard to the BSE crisis reveals, in fact, that the EU engaged in a "*cycle of avoiding and postponing the resolution of problem*"[129]. This is why the current phase of EU food law can be understood only as far as the "consumers' trauma to which it responds is understood as well[130]. As Ellen Vos underlines "*consumers were shocked by the realization that the agro-food industry was producing beef by feeding meat and bone meal to ruminants, turning herbivores into carnivores and carnivores into cannibals*"[131].

BSE is a type of transmissible spongiform encephalophaty (TSE), a degenerative disease of the central nervous system, which may occur in several animal species, such as cattle and sheep[132]. In 1986 the 'mad cow' disease was, for the first time, identified in the UK. For almost a decade after this discovery, the British government adamantly denied that the disease could be transmitted to humans[133].

Moreover, in 1996, epidemiologists in the UK reported that that a link between BSE and Creutzfeldt-Jacob disease[134] could not be ruled out, and effectively confirmed that BSE could be transmitted to humans (by eating food contaminated with the brain,

[127] VOS E., *EU Food Safety Regulation in the Aftermath of the BSE Crisis*, in *Journal of Consumer Policy*, 2014, p.13
[128] Report of the Temporary Committee of Inquiry into BSE, set up by the Parliament in July 1996, on the alleged contraventions or maladministration in the implementation of Community law in relation to BSE, without prejudice to the jurisdiction of the Community and the national courts of 7 February 1997, A4-0020/97/A, PE 220.544/fin/A.
[129] SALMEH K. F., *How Does the European Union Solve Crises - With Solutions or by Avoidance - A Study of the Mad Cow Disease Crisis*, in *Georgia Journal of International and Comparative Law*, Vol. 27, Issue 1, 1998, p. 263
[130] See note 136, p. 208
[131] See note 139
[132] GROSSMAN M. R., *Animal Identification and traceability under the US Animal Identification System* in *Journal of Food Law and Policy*, 2006, p 231
[133] ARCI JENISH D., *A Disturbing Link to the 'Mad Cow' Disease*, in *109 MACLEAN'S*, 1996, p. 36
[134] Creutzfeldt-Jacob disease (Vcjd) is a TSE (like BSE) characterised by a spongy degeneration of the brain and its ability to be transmitted

spinal cord, or digestive tract of infected carcasses[135]). The evidence of a connection was so strong that many countries, such as the United States and some Member States, have instituted bans on British beef and beef by-products[136].

The Council, in order to prevent the spread of the disease, issued directives requiring Britain to comply with a number of safety measures. On March 27, 1996, the Commission addressed the problem, issuing a blanket ban[137] on British exports toward Member States as well as third states. Yet, several national governments expressed concerns that the wrong management of the crisis might have been the result of a misconduct not only of the British authorities but also of the Commission[138]. Therefore, in 1996 a Temporary Committee of Inquiry into BSE was set up and its report revealed many mistakes and failures made by the Commission in the handling of the crisis[139].

The following are among the main reasons of negligence and maladministration: "*It has given priority to the management of the market ,as opposed to the possible human health risks*", "*it has tried to follow a policy of downplaying the problem*", "*it did not carry out inspections between June 1990 and May 1994" (a policy of "disinformation*" when the disease was at its height), "*too much weight was placed on the role of the Scientific Veterinary Committee*" (due to the pressure exerted by the British members of that committee, it was accused to be influenced by British thinking), "*lack of transparency*".

[135] "Commonly Asked Questions About BSE in Products Regulated by FDA's Center for Food Safety and Applied Nutrition (CFSAN)", Center for Food Safety and Applied Nutrition, Food and Drug Administration, 2005

[136] BOSELEY S., *How the Truth was Butchered*, in *World Press Review*, June 1999, p.145

[137] Commission Decision 96/239/EC on emergency measures to protect against bovine spongiform encephalophathy, (1996) OJ L 78/47.

[138] BLACKBURN P., *EU Parliament Warns Brussels Over BSE*, in *EUR. Bus. REP*., 1997, p. 214

[139] Report of the Temporary Committee of Inquiry into BSE, set up by the Parliament in July 1996, on the alleged contraventions or maladministration in the implementation of Community law in relation to BSE, without prejudice to the jurisdiction of the Community and the national courts of 7 February 1997, A4-0020/97/A, PE 220.544/fin/A.

Yet, the Enquiry Committee did not confine itself to critical comments, but went further, making recommendations for restructuring the European food system[140].

Therefore, in order to face all these issues, the President of the Commission[141] first and the Commission then [142] announced that a "new approach" to consumer health and food safety ought to be adopted and that an internal re-organization of the Directorates dealing with human health was needed. In particular, the DG XXIV was renamed into the Directorate-General on consumer policy and Consumer Health protection (now DG SANCO) and the relevant scientific committees, dealing with industrial and agricultural policies were placed under its authority[143]. The rationale of this choice was to avoid what has already happened in the past: the influence from non-scientific bodies, which could create an interference of economic interests with health protection issues. Apart from this institutional reform of the Commission, from a substantial point of view a crucial step forward was undertaken.

In addition to the 1997 New approach[144], in the April of the same year, the Commission publish its Green Paper on the General Principles of Food Law in the EU[145]. These documents laid down several goals for Community food law "*to ensure a high level of protection of public health, safety and the consumer, to ensure the free movement of goods within the internal market and to ensure the competitiveness of European industry and enhance its export prospects, to ensure that the legislation is primarily based on scientific evidence and risk assessment, to place the primary responsibility for food safety on industry, producers and suppliers*"[146].

[140] VAN DER MEULEN B., *Food law: development, crisis and transition* in VAN DER MEULEN B., VAN DER MEULEN M. (eds.) *European food law handbook*, Wageningen, 2014, p.212
[141] Speech of 18 February 1997, Bull EU 1/2 1997.
[142]Communication from the Commission on consumer health and food safety, COM (97) 183 final. http://europa.eu.int/comm/dgs/health_consumer/index_en.htm
[143] KNUDSEN G., MATIKAINEN-KALLSTROM M., Joint Parliamentary Committee Report on food safety in the EEA, 1999
[144] COM (97) 183 Final
[145] Commission Green Paper on the general principles of food law in the European Union, COM (97) 176 Final.
[146] COM (97) 176 Final

These objectives made clear the emphasis on food safety and consumer protection, that this new approach entailed. In fact, until the outbreak of the "mad cow" disease, the Community food regulation traditionally resorted to committees[147] and was led mainly by pragmatic considerations. On the one hand, this pragmatic approach could be explained by the fact that, at the beginning, the Community was not designed to deal with risk regulation[148] and that even European food safety was subordinated to the development of the internal market. On the other hand, this committee-based structure was generally approved and trusted at the EU level as well as at the national one and this attitude was confirmed by the case-law[149] of the ECJ too.

A leading case in this regard was *Commission v. Germany* (commonly known as German beer purity law). It was about a German law, that in order to ensure the 'purity' of the German beer (which traditionally is produced with only four ingredients), laid down the prohibition of importing beers, containing additives. The Court ruled that in order to restrict the market, by relying on Article 36 TFEU and to assess whether or not a certain product may cause a risk to public health, Member States shall take into account "*on the one hand, the findings of international scientific research, and in particular of the work of the Community's Scientific Committee for Food, the Codex Alimentarius Committee of the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization, and on the other hand, the eating habits prevailing in the importing Member State*"[150].

Therefore, such committees (in particular the Scientific Committee for Food) were considered as the proper forum for decision-making and scientific consultation as far

[147]The most important ones were the Scientific Committee on Foodstuffs (SCF), the Standing Committee on Foodstuffs (StCF) and the Advisory Committee on Foodstuffs (ACF)
[148] VOS E., *EU Food Safety Regulation in the Aftermath of the BSE Crisis*, in *Journal of Consumer Policy*, 2014, p. 231
[149] See, for instance, Case 178/84, *Commission v. Germany* [1987] ECR 1227; Case 247/84, *Motte* [1985] ECR 3887; Case 304/84, *Muller [*1986] ECR 1511.
[150] Case 178/84, *Commission v. Germany*, 1987 par. 44

as questions on human health protection were at stake. “Yet, the BSE crisis, shattered this image” [151].

As explained above, in fact, the ‘mad cow disease’ albeit not being nor the first neither the worst disease in terms of death, disclosed several deficiencies in the Community approach to food safety regulation. This is the reason why, in its communication, the Commission took the initiative to adopt a more conceptual approach to food safety. More precisely after reminding that in his speech before the European Parliament on 18 February 1997 President Santer made "*a plea for the gradual establishment of a proper food policy which gives pride of place to consumer protection and consumer health*" it emphasized that “*food safety and consumer health are at the core of the new political departure… to achieve these objectives the Commission has reorganised and intends to reinforce three complementary instruments: scientific advice, risk analysis and control*”[152]. Moreover, in the Green Paper was underlined the wish “*to ensure that the regulatory framework covers the whole food chain "from the stable to the table*”[153]. Therefore, such document laid down the structure of a legal system no more based on an ad-hoc approach and capable of getting a firm grip on food production[154].

Yet, subsequent food safety scandals, such as the “Dioxin affair”[155] in Belgium and fraudulent practices of producers brought to light further shortcomings in the EU food law, underlying the need to improve the protection of public health all over Europe. In fact, as it was rightly pointed out, “*the world's faith in the EU's future as a globally*

[151] See note 160
[152] Communication from the Commission on consumer health and food safety, COM (97) 183 final
[153] COM (97) 176 Final
[154] VAN DER MEULEN B., *Food law: development, crisis and transition* in VAN DER MEULEN B., VAN DER MEULEN M. (eds.) *European food law handbook*, Wageningen, 2014, p. 213
[155] In the spring of 1999, dioxin was introduced into the Belgian food supply, including exports, via contaminated animal fat used in animal feeds supplied to Belgian, French and Dutch farms. Hens, pigs and cattle ate the contaminated feed and high levels of dioxin were found in meat products as well as eggs. For a general overview, see LOCK C., POWEL D., *The Belgian Dioxin Crisis of the Summer of 1999: a case study in crisis communications and management*, February 1, 2000 Technical Report

powerful entity will rapidly decline if it cannot quickly and effectively provide solutions to situations such as the BSE crisis"[156].

1.2.3 The provisions of the Amsterdam Treaty as a stronger legal basis for the new EU food law

The mad cow disease caused such a huge debate, to influence also the political agenda of the Inter-Governmental Conference on the Treaty of Amsterdam[157] in 1997. To ensure better policies, several provisions were renewed and for what concerns health and safety protection, reformulation of Articles 95, 152 and 153 TEC are worthy to be analyzed. The rationale of these changes was to legally shape the willing of the Community as well as of the Member States not to repeat the mistakes occurred in the BSE affair[158].

Article 95 (now Article 114 TFEU[159]) represents the legal basis for the approximation of laws between Member States and paragraph 3, in particular, refers to the idea of including also non-market values in the process of harmonization. This concept was clarified in the famous *Tobacco advertising case*[160], where the Court made clear that as far as the conditions for recourse to Article 114 TFEU as a legal basis are fulfilled, "*the Community legislature cannot be prevented from relying on that legal basis on the ground that public health protection is a decisive factor in the choices to be made. On the contrary, the third paragraph of the same article provides that health requirements*

---

[156] SALMEH K. F., *How Does the European Union Solve Crises - With Solutions or by Avoidance - A Study of the Mad Cow Disease Crisis*, in *Georgia Journal of International and Comparative Law*, Vol. 27, Issue 1 (1998), pp. 249-264

[157] Officially the Treaty of Amsterdam amending the Treaty on European Union, the Treaties establishing the European Communities and certain related acts, OJ C 340, 10.11.1997, p. 1-144. It was signed on 2 October 1997 and entered into force on 1 May 1999.

[158] VOS E., *EU Food Safety Regulation in the Aftermath of the BSE Crisis*, in *Journal of Consumer Policy*, 2014, p. 235

[159] Article 114 (ex Article 95 TEC): "Save where otherwise provided in the Treaties, the following provisions shall apply for the achievement of the objectives set out in Article 26. The European Parliament and the Council shall, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee, adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.

[160] Case C-376/98, *Germany v. Parliament and Council* [2000] ECR 08419

are to form a constituent part of the Community's other policies and expressly requires that, in the process of harmonisation, a high level of human health protection is to be ensured."[161]

While the commitment to ensure a high level of protection of the mentioned good was already included in the article, the Treaty of Amsterdam included the need to take into account "*the new development based on scientific facts*"[162], in order to include more and more science in the decision-making process. This reference is of obvious importance in the food sector especially when considering the role of the European Food Safety Authority (EFSA). As reminded above, the Court in its case law[163] has always payed attention to the interplaying between the European legislator and the scientific community.

In *Angelopharm* for instance, the Court clearly said that: "*The drafting and adaptation of Community rules governing products are founded on scientific and technical assessments which must themselves be based on the results of the latest international research and which are frequently complex. This is particularly the case where it is a question of assessing whether or not a substance is injurious to human health*" [164] . While paragraph 3 is about the action carried out by the EU Commission, paragraphs 4 and 5 entitle Member States to derogate from harmonizing measures as far as it is necessary to protect certain public goods. Thanks to the Treaty of Amsterdam, the new paragraph five[165] in particular, states that "*If after the adoption of a harmonisation measure […], a Member State deems it necessary to introduce national provisions based on new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State arising*

[161] Case c-376/98 Paragraph 88
[162] Article 114, paragraph 3 "The Commission, in its proposals envisaged in paragraph 1 concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts"
[163] See, inter alia, Case 178/84, *Commission v. Germany* [1987] ECR 1227; Case 247/84, *Motte* [1985] ECR 3887; Case 304/84, *Muller* [1986] ECR 1511
[164] Case C-212/91, *Angelopharm v. Freie und Hansestadt Hamburg* [1994] ECR I-171, par. 31
[165] On Art 114 TFEU par. 5 see Joined Cases C-439/05 and C-454/05 *Land Oberösterreich and Republic of Austria v Commission of the European Communities*

after the adoption of the harmonisation measure, it shall notify the Commission of the envisaged provisions as well as the grounds for introducing them".

Article 168[166] TFEU was changed in 1997 too. It provides for a high level of protection of public health in the definition and implementation of all Union policies and activities. While in the past they shall only "contribute to" it, now such level of protection "shall be ensured". Furthermore, paragraph 4 (b) deals with the Council and Parliament action with regard to veterinary and phytosanitary measures[167].

Last but not the least, the Treaty of Amsterdam added to Article 153 TEC (now Article 169 TFEU) that "*the Union shall contribute to protecting the health, safety and economic interests of consumers*"[168]. This provision has been (inter alia) part of the legal basis for the adoption of the General food law Regulation[169]. As already underlined, after the BSE and other food scandals, one of the main objectives pursued by the Commission was "to restore and maintain consumer confidence"[170].

Its vision on the prospective food system was laid down in the White Paper on Food Safety[171]. After reminding that "*a series of crises concerning human food and animal feed (BSE, dioxin etc.) has exposed weaknesses in the design and application of food legislation within the EU*" the Commission has decided "to include the promotion of a high level of food safety among its policy priorities over the next few years... particular

[166] Ex Article 152 TEC
[167] Art 168 TFEU par. 4: "By way of derogation from Article 2(5) and Article 6(a) and in accordance with Article 4(2)(k) the European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in this Article through adopting in order to meet common safety concerns: (b) measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health"
[168] Art 169 TFEU, par.1 "In order to promote the interests of consumers and to ensure a high level of consumer protection, the Union shall contribute to protecting the health, safety and economic interests of consumers, as well as to promoting their right to information, education and to organise themselves in order to safeguard their interests"
[169] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, 1.2.2002, pp. 1-24
[170] VAN DER MEULEN B., *Food law: development, crisis and transition* in VAN DER MEULEN B., VAN DER MEULEN M. (eds.) *European food law handbook*, Wageningen, 2014, p. 214
[171] White paper on food safety of 12 January 2000, COM/99/0719 final

attention must be focused on improving quality standards and reinforcing systems of checks throughout the food chain, from farm to table"[172]. The measures to reach such goal were: the establishment of an independent European Food Authority with responsibility for independent scientific advice on all aspects relating to food safety, operation of rapid alert systems and communication of risks, an improved legislative framework covering all aspects of food products "from farm to table", greater harmonisation of national control systems and dialogue with consumers and other stakeholders.

Only two years later the cornerstone of new European Food Law was adopted: Regulation 178/2002. Even though this Regulation cannot be qualified as a code comprising all food legislation, it is a pillar in the general part of food law. In fact, while the principle of mutual trust encouraged and allowed the free movement of food in the EU internal market, it was mainly thanks to the adoption of secondary law (i.e. regulations and directives) that only safe food may enjoy such freedom[173].

In fact, by providing general principles and establishing the EFSA, the main objective that the General Food law (GFL) seeks to secure, is an elevated level of protection of public health and consumer interests when it comes to food products and the precautionary principle, in particular, plays a key role in this regard.

[172] See note 187
[173] ACCONCI P., *Riflessioni sull'accezione di qualità dei prodotti agroalimentari rilevante nel diritto dell'Unione europea*, in *Studi sull'integrazione europea*, 2016, p. 271

1.2.4 Precautionary principle in EU and in the 'General Food law'

"*The current commercially driven developments in areas such as the agricultural and food industries involve issues which are at the frontiers of scientific understanding*"[174]. As the GFL confirms in Article 6[175] food law is science-based and this principle lies at the core of the "new approach" to EU food law as "food safety law"[176]. First, it is necessary to clarify the meaning of "food safety". Under EU secondary law, in fact, the expression "food security" can be understood only as far as a fundamental distinction is considered. While the Italian term "sicurezza alimentare" may create confusion, in English becomes clear that both "food safety" and "food security" fall under this concept[177].

The first refers to food safety from the point of view of health protection (human as well as animal welfare). The second, addressing the issue from an economic prospective, means security of supply, regularity, stability and adequacy of food products. Only the first meaning is considered in the present work. A definition of the term can be found in the Codex Alimentarius[178] which states that "food safety" is the "*assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use*."[179] In the GFL there is no such a definition but it only provides for a ban on marketing unsafe food, explaining when food is deemed to be unsafe[180].

---

[174] LITTLE G., *BSE and the Regulation of Risk*, in *Modern Law Review*, 2001, p. 730

[175] Regulation (EC) No 178/2002 Art 6 par.1 "In order to achieve the general objective of a high level of protection of human health and life, food law shall be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure

[176] SZAJKOWSKA A., VAN DER MEULEN B., *The General Food Law: general provisions of food law*, in VAN DER MEULEN B., VAN DER MEULEN M. (eds.) *European food law handbook*, Wageningen, 2014, p. 244

[177]CAPELLI F., *La sicurezza alimentare nell'Unione Europea e in Italia, in Diritto comunitario e degli scambi internazionali*, fasc. 4, 2016, p.664

[178] The Codex Alimentarius, or "Food Code" is a collection of standards, guidelines and codes of practice which contribute to the safety, quality and fairness of this international food trade, adopted by the Codex Alimentarius Commission.

[179] Recommended International Code of Practice-General Principles of Food Hygiene, CAC/RCP 1-1969, rev. 4 (2003), p. 7

[180] Regulation 178/2002 (GFL) Art 14 par.1 "Food shall not be placed on the market if it is unsafe"

Yet, since in the area of food legal standards and science are often interrelated, the present Regulation includes, as a leading factor to ensure health protection, the precautionary principle[181]. In order to deal with it, it shall be useful to analyse its international dimension first and then moving to its application under EU law. The precautionary principle deals with the decision-making process as far as scientific uncertainty is concerned. Science, in fact, has its own limits: experiments could be improperly conducted, scientific knowledge may be inconsistent world-wide and inconclusive results may come out.[182]

At the international level, it has often been used in defence of trade restrictions induced by environmental protection considerations[183]. The traditional approach has always been led by the consideration that risk management measures shall be adopted only when a potential danger for health or environment has been proven by the scientific community.

The precautionary principle, on the other hand substantially changes such approach[184], since it imposes the adoption of protective measures even if there is no conclusive scientific evidence on the alleged hazardous effect of a certain product or activity. Therefore, it counterpoises the so-called "wait and see" principle[185] to a precautionary approach, when evidences are less than concrete.

The principle was first defined by the 1992 UN Conference on Environment and Development in Rio de Janeiro. The Rio Declaration states: "*In order to protect the environment, the precautionary approach shall be widely applied by States according*

[181] GFL Art 7 par.1 "In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment"

[182] CHANG-FA L., *Risks, scientific uncertainty and the approach of applying precautionary principle*, in *Medicine and Law*, 2009, p.284

[183] VEINLA H., *Free Trade and the Precautionary Principle* in *Juridica International*, Vol. 8, 2003 p. 187

[184]SAFRIN S., *Treaties in collision. The Biosafety Protocol and the World Trade Organization Agreements*, in *American journal of International law*, 2002, vol.96, Issue 3, p 610-612

[185] WIRTH D., *The role of science in the Uruguay Round and NAFTA Trade Disciplines*, in *Cornell International Law Journal*, 1994, No. 27, p.834

to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation"[186].

The gradual recognition of the principle as a general rule of international law, led the ECJ to rule on it in its case-law[187] during the 1980'. In particular, the first time in which the Court expressed its own assessment on the precautionary principle was in *Sandez*, a case about the potential harmful effects of vitamins A and D. At that time, it was generally accepted that excessive intake of vitamins A and D was harmful to health, but the scientific community was no able to define what exact amounts was dangerous. The Court, in this regard ruled that:" *in so far as there are uncertainties at the present state of scientific research it is for the Member States, 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*"[188]. As Jiang rightly pointed out, "*this was the precautionary principle without a name*"[189].

Therefore, while at the EU level the precautionary principle has been immediately linked the free movement of goods and food[190], at the international level, the application of such principle in the area of food safety, has occupied a central stance in many disputes. The rationale of the "offensive" nature of the principle can be found in what U. Beck, describes as a "Risk society"[191]. In its opinion a gradual shift from

[186] United Nations Conference on Environment and Development, Rio de Janeiro, Braz., June 3-14, 1992, Rio Declaration on Environment and Development, Principle 15, U.N.Doc. A/CONF.151/26/Rev.i (Vol. I), Annex I (Aug. 12, 1992).
[187] See, inter alia, Case C-174/82 *Sandoz*, 1983, case C-53/80, *Prosecutor v Koninklijke Kaasfabriek Eyssen BV*, 1981, Case C-227/82, *Leendert van Bennekom*, 1983
[188] Case C-174/82 Sandoz, 1983, par. 16
[189] JIANG P., *A Uniform Precautionary Principle under EU Law*, in *Peking University Transnational Law Review*, Vol. 2, Issue 2 (2014), p. 495
[190] BOCCHI M., *La dimensione internazionale del principio di precauzione e la sua applicazione nel diritto europeo e statunitense alla prova nel negoziato sul TTIP*, in *La Comunità Internazionale*, Fasc.2/2017, p. 257
[191] BECK U., *Risk society: Towards a new modernity*, London, 1992

"distributive welfare" towards "distributive risks" is taking place and such tendency produces its effects also on social and political systems.

In 1992 the precautionary principle was incorporated by the Maastricht Treaty into what is now Article 191 of the TFEU[192]. The TFEU, however, does not define it and therefore the EU institutions, in particular the Court and the Commission, have been left to fill in the gaps. First, as the ECJ underlined "although the precautionary principle is mentioned in the Treaty only in connection with environmental policy, it is broader in scope…it is intended to be applied in order to ensure a high level of protection of health, consumer safety and the environment in all the Community's spheres of activity"[193]. In this regard, a famous application of this principle can be found in the judgment of the Court on the validity of the Commission's decision[194] to ban the exportation of beef from UK in the context of the BSE crisis. Here the Court confirmed that "*where there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent*".[195]

This ruling represented a watershed for what concerns the interpretation of such principle, for two main reasons. First, since the objective of the case was the annulment of the Commission's decision, it means that the Court allowed the use of the precautionary principle to challenge both national and European measures. Second, while not setting a minimum threshold of the risk needed, it focused only on the

[192] Article 191(2) of the TFEU reads: "Union policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Union. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay.

[193] Case T-74/00, *Artegodan GmbH and Others v Commission of the European Communities*, 2002 E.C.R. 11-04945, par. 183.

[194] Commission decision 96/239/EC of 27 March 1996 on emergency measures to protect against bovine spongiform encephalopathy

[195] Cases C-157/96, par. 63,64 *The Queen v Ministry of Agriculture, Fisheries and Food and Commissioners of Customs & Excise, ex parte National Farmers' Union and Others* and C-180/96, *United Kingdom of Great Britain and Northern Ireland v Commission of the European Communities.* The statement in the BSE judgments was cited also in other cases. See, inter alia, Case T-199/96 and case T-70/99

existence of a potential risk as factor triggering the application of a precautionary approach, without explicitly mentioning the precautionary principle itself[196].

Owing to the increasing attention paid this issue, few years later the Commission published its Communication[197] aimed at informing of the manner in which the principle shall apply and be implemented in EU policies and reminding that recourse to such principle presupposes that "*potentially dangerous effects deriving from a phenomenon, product or process have been identified, and that scientific evaluation does not allow the risk to be determined with sufficient certainty*"[198].

Yet, when it comes to debated issues such as the minimum threshold of risk needed, this document has not been very useful. In fact, it said that the assessment about whether or not the level of risk is "acceptable" is an "eminently political responsibility"[199]. Here we come to the very essential nature of the principle at stake: it is a discretionary rule and the gap between scientific uncertainty and protective measures "*can only be bridged by human discretion*"[200].

An important case in this regard is *Pfizer*[201] in which the Court made clear that, owing to the possibility that a full risk assessment may require long and detailed scientific research, "*unless the precautionary principle is to be rendered nugatory, the fact that it is impossible to carry out a full scientific risk assessment does not prevent the competent public authority from taking preventive measures, at very short notice if necessary, when such measures appear essential given the level of risk to human health which the authority has deemed unacceptable for society*"[202].

---

[196] CHEYENE I, *Taming the Precautionary Principle in EC Law: Lessons from Waste and GMO Regulation*, in *Journal for European Environmental & Planning Law*, 2007, p. 468
[197] Communication from the Commission on the Precautionary Principle, § 5.2.1, COM (2000) 1 final (Feb. 2, 2000)
[198] COM (2000) I Final, par. 4
[199] COM (2000) I Final, par. 5
[200] JIANG P., *A Uniform Precautionary Principle under EU Law*, in *Peking University Transnational Law Review*, Vol. 2, Issue 2 (2014), p. 496
[201] Case T-13/99, *Pfizer Animal Health SA v. Council of the European Union*, 2002 E.C.R. II03305. The case concerned the use of a particular antibiotic in animal feed which was banned by the Commission.
[202] *Pfizer*, par. 160

Even though the decision to act or not has a political nature, legal constraints shall be respected. This is why the Commission provides for several "guidelines for applying the precautionary principle"[203], in order to avoid abuses and unacceptable trade restrictions. First, the measures concerned must be proportionate[204], meaning commensurate with the level of protection desired. Second, they must not have a discriminatory[205] character, meaning that like situations must be treated as like as well as non-comparable situations must be treated differently. Third, measures must be consistent[206] with those ones already adopted in similar cases. Fourth, there is a call for a cost-benefits[207] analysis when the choice among acting or not has to be made. Fifth, the measures must always take into account scientific developments[208] and be modified in a consistent manner. Since political decisions are difficult to be scrutinized from a legal point of view, such leading rules make the precautionary principle judicially reviewable, at least in procedure if not in substance[209].

Therefore, at the end of the day what lies at the core of this principle is a proper balance between economic and non-economic values, between the need to ensure "the freedoms and right of individuals, industry and organisations"[210] and the need to eliminate, or at least reduce the risk of negative effects to health and environment. If, on the one hand, there are merits to this approach, on the other hand the Communication has also been criticized. One of the reasons is that it does not provide for sufficient restrictions to avoid disguised protective measures[211].

[203] COM (2000) I Final, par. 6
[204] COM (2000) I Final, par. 6.3.1
[205] COM (2000) I Final, par. 6.3.2
[206] COM (2000) I Final, par. 6.3.3
[207] COM (2000) I Final, par 6.3.4
[208] COM (2000) I Final, par. 6.3.5
[209] See note 212 p.498
[210] COM (2000), I Final, par. 1
[211] For a critical overview of the Communication see MCNELIS N., *EU communication on the precautionary principle,* in *Journal of International Economic Law*, 2000, p. 545

In this regard, also the US government, albeit welcoming the EU's efforts, expressed the fear that in the field of food standards, the application of the precautionary principle could lead to a reliance on political considerations rather than scientific ones[212].

Moreover, the Commission did not go further in respect of what the case-law of the Court and the legal and scientific practice had already said[213], such as the broad scope of the principle, the right for States to set their own level of protection and so on. Furthermore, as already said, a minim threshold of the risk needed as a triggering factor of the principle has not been set.

Yet, in this regard, the Communication has been pivotal for the following case-law of the ECJ[214], which was involved in a strong dialogue on the issue with the EFTA Court. In particular, in *Pfizer*[215] and *Alpharma*[216] the Court of First Instance, indirectly recalling the case *EFTA Surveillance Authority v. Norway*[217], clarified that "preventive measure cannot properly be based on a purely hypothetical approach to the risk, founded on mere conjecture which has not been scientifically verified"[218]. Moreover, in the following cases an autonomous dimension to the precautionary principle as a general principle of EU law has been recognized.[219]

For what concerns its application under EU food law, this principle is now included in Article 7 of the GFL. Food law, in fact, is based on a risk-analysis process, which consists of three key elements: risk assessment, risk management and risk communication. The application of such principle "*adds subtlety to the risk-analysis*

[212] US government reaction on the Commission Communication, expressed at the April 10-14 meeting of the Codex Alimentarius Commission's General Principles Committee in Paris, in Inside U.S. Trade, vol 18, n 14, 2000
[213] BOCCHI M., *La dimensione internazionale del principio di precauzione e la sua applicazione nel diritto europeo e statunitense alla prova nel negoziato sul TTIP*, in *La Comunità Internazionale*, Fasc.2/2017, p. 259
[214] HEYVAERT v., *Facing the Consequences of the Precautionary Principle in European Community Law* in *European Law Review*, 2006, pag. 190
[215] Case T-13/99, *Pfizer Animal Health SA v Council of the European Union*, 2002 II-03305
[216] Case T-70/99 *Alpharma Inc. v Council of the European Union*, 2002 II-03495
[217] Case E-3/00, *EFTA Surveillance Authority v. Norway*, April 2001
[218] Case T-70/99 *Alpharm*a, par. 143
[219] See Case T-392/02, *Solvay Pharmaceuticals BV v Council of the European Unio*n and Case T-74/00, *Artegodan GMbH v. Commission*

principle"[220]. At the international level, recourse to the precautionary principle has been an issue of controversy in particular in the context of the World Trade Organization. As we will see in the next paragraph, the main reason is that under the SPS agreement, the application of such principle may be used as a tool for disguised protective measures[221].

1.3 The third dimension of food law: The relationship between European and international food law in the framework of the Common Commercial Policy

After the examination of the European dimension of food law, the focus of this parahraphs will shift on the opening of the EU market towards third countries and a comparison between the EU legal order and international rules addressing food safety will be made more clearly.

From its beginning, in fact, there was large agreement about the fact that the European internal market should also be at the same time, opened to products coming from outside the Union and able to export abroad its own goods (food products included) [222]. Definetly, the membership of Member States and of the European Union in the in the GATT first and in the World Trade Organization then, has been crucial to develop commercial relationships with third countries. Consequently, "*both national and European food law had to take the international commitments concerning food standards into consideration*"[223] In fact, the more free-trade is pursued, the more shall

[220] SZAJKOWSKA A., VAN DER MEULEN B., *The General Food Law: general provisions of food law*, in VAN DER MEULEN B., VAN DER MEULEN M. (eds.) *European food law handbook*, Wageningen, 2014, p. 246
[221] See note 229
[222] KAYAERT G., *The European Market for Food Products* in *Food and Drug Law Journal*, Vol. 51, Issue 4, 1996, p. 717
[223] SCHEBESTA H., VAN DER MEULEN B., VAN DER VELDE M., *International food law*, in VAN DER MEULEN B., VAN DER MEULEN M. (eds.) *European food law handbook*, Wageningen, 2014, p. 75. On the status of the WTO Agreements in the European legal systems see Joined Cases C–120/06 P and 121/06 P, Fabbrica italiana accumulatori motocarri Montecchio SpA (FIAMM) and Others v. Council and Commission and Giorgio Fedon & Figli SpA and Others v. Concil and Commission [2008] ECR I–6513 (also known as *FIAMM and Fedon*). FIAMM and Fedon export to the USA were subject to increased tariffs ad valorem after the protracted violation of WTO obligations by the EC in the bananas litigation. Therefore, they sued the Council and the Commission before the Court of First Instance claiming their non-contractual liability for unlawful acts. Yet, the Court of Justice denied the direct effect of the WTO provisions, concluding that "given their nature and structure, those agreements are not in

be the need to protect non-trade values, such as human and animal health, and finding the proper balance between the two issue, is not always an easy task.

1.3.1 The European Union as a WTO member and Article 207 TFEU

As Weiler rightly pointed out, it is not possible to analyze cases concerning the EU internal market "without a firm grasp of the GATT"[224] and of the WTO. The rationale is that the interlocking system of multilateral trade has often had a huge impact on the EU legal system. In order to compare the free movement of goods in the European Union and in the WTO, first of all the differences between these two systems shall be understood, since they have undergone different developments and were established to achieve different purposes[225]. While the aim of the GATT was to liberalize trade in goods, in the EU a far-reaching project of economic and political integration, of harmonization of laws was undertaken[226].

The General Agreement on Tariffs and Trade of 1947 was the first world-wide general commercial agreement in history, whose purpose was to enhance international trade, by gradually reducing tariff-barriers. Even though it was originally designed to serve only as a temporary expedient until the ratification of the Habana Charter establishing the International Trade Organization (ITO), at the end of the day the GATT 47' has been for almost fifty years the only instrument regulating world-wide commercial relationships.

---

principle among the rules in the light of which the Court is to review the legality of measures adopted by the Community institutions" par.111. The Court admitted the direct effect of WTO obligations only in marginal cases such as Case 69/89, *Nakajima v. Council* [1991] ECR I–2069 and Case 70/87, *Fediol v. Commission* [1989] ECR 1781. For a general overview on the issue see DANI M., *Remedying European Legal Pluralism: The FIAMM and Fedon Litigation and the Judicial Protection of International Trade Bystanders*, in *The European Journal of International Law*, Vol. 21, p. 303-340

[224] WEILER J. H.H., *Epilogue: Towards a Common Law of International Trade*, in *THE EU, THE WTO, AND THE NAFTA-TOWARDS A COMMON LAW OF INTERNATIONAL TRADE?*, Oxford University Press, Oxford, 2000

[225] PERISIN T., *Balancing Sovereignty with the Free Movement of Goods in the EU and the WTO - Non-Pecuniary Restrictions on the Free Movement of Goods* in *Croatian Yearbook of European Law & Policy*, Vol. 1, p. 111

[226] DILLON S., International Trade and Economic Law and the European Union, Oxford, 2002 p 2-3

In fact, when the ITO failed "GATT remained as the positive achievement, in the field of trade, of the ambitious postwar vision of world cooperation in the political, economic, social, and cultural spheres"[227]. Since the Treaty of Rome has been adopted only in 1957, Member States were already Contracting Parties of GATT 47' and the Community could not be counted as a Contracting Party as well[228]. From a legal point of view the possibility to create a custom union was set forth in Article XXIV[229] GATT, which provided an exception to the "principle of most-favoured nation status". As far as the conditions set in this provision were met, it was possible to create regional trading blocs, in the form of a free trade area as well as of a custom union.

Albeit the existence of this exception on the one hand and of Article 234[230] in the Rome Treaty, the relationship between GATT and the Community has been not easy at all[231]. In particular, after the entry into force of the customs union in 1968, as the Court stated in 1972 "the Community has assumed the functions inherent in the tariff and trade policy, progressively during the transitional period and in their entirety on the expiry of that period… by conferring those powers on the Community, the Member States showed their wish to bind it by the obligations entered into under the General Agreement."[232]

Therefore, by investing the Community of the powers to act on their behalf in the GATT institutions and meetings, the Member States were *de facto* substituted inside GATT by the Community[233]. Strictly speaking, as the EC did not formally become a

[227] BRONZ G., *International Trade Organization: The Second Attempt*, in *Harvard Law Review*, 1956, p. 441
[228] *WTO-Agreement* in *Columbia Journal of European Law*, Vol. 1, Issue 2 1995, p. 339
[229] Now Article XXIV of GATT 94'
[230] Now Article 351 TFEU par. 1 "The rights and obligations arising from agreements concluded before 1 January 1958 or, for acceding States, before the date of their accession, between one or more Member States on the one hand, and one or more third countries on the other, shall not be affected by the provisions of the Treaties" Par. 2 "To the extent that such agreements are not compatible with the Treaties, the Member State or States concerned shall take all appropriate steps to eliminate the incompatibilities established…"
[231]SCISO E*., L'organizzazione mondiale del commercio,* in *Appunti di diritto internazionale dell'economia*, Torino, 2017, p. 157
[232] Joined Cases 21 to 24/72, *International Fruit Company*, 1972 E.C.R. 1219, par. 14-15
[233] See note 238, p. 339

contracting party it was neither a substitution nor a succession of its Member States within the framework of GATT.

Yet, the issue of the Community membership in the "world trade system" has been again a matter of debate when on April 1994, representatives of the governments of 125 Contracting parties of the GATT signed the Final Act embodying the results of the Uruguay Round multilateral trade negotiations. As the Council emphasized, these were the "*most complex negotiations in world history*"[234].

The role to negotiate had been assigned to the Commission, on behalf of the Community and its Member States. But the more sectors the agreements covered, the more unclear was whether or not all the issues under negotiation were part of the competences of the EC.[235] Even though the creation of an international trade organization was not the main objective pursued, eventually negotiating partners decided to create the WTO as a "political platform for world trade negotiations"[236].

This system was based on the so-called "single undertaking approach" meaning that in order to be part of the WTO Parties have to accept the whole package or nothing at all. Such compulsory acceptance concerned the 'multilateral trade agreements' forming an integral and substantive part of the WTO Agreement: the General Agreement on Trade in Goods (the so-called GATT 1994, consisting of GATT 1947 plus successive amendments and new protocols), the first General Agreement on Trade in Services (GATS), an Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs), an Understanding on Rules and Procedures Governing the Settlement of Disputes and a Trade Policy Review Mechanism.

Owing to the "single undertaking approach" the question on the competence of the European Community to conclude the Agreement establishing the World Trade

[234] Observations of the Council of the European Union to the Commission's request for an advisory opinion to the Court of Justice, then Opinion 1/94
[235] HILF M., *The ECJ's Opinion 1/94 on the WTO - No Surprise, but Wise?*, in *European Journal of International Law*, 1995, p. 247
[236] SCHEBESTA H., *International food law*, in VAN DER MEULEN B. (ed.) *EU Food Law Handbook*, Wageningen, 2014, p. 89

Organization and, in particular the GATS and the TRIPs was raised before the Court. On the one hand, the Commission owing to many overlaps between the trade in goods and several aspects of GATS and TRIPs took the view that the Community alone would be competent to conclude the WTO agreement and its annexes. On the other hand, the Council and several Member States, maintained that such competence was to be shared between the Member States and the Community. Indeed, "*States are sensitive when it comes to limitations of their foreign relations powers, which are still considered to be the hard core of the ageing concept of national sovereignty*[237]".

On the issue, the Court of Justice delivered its most voluminous advisory opinion 1/94[238]. For what concerns the status of the European Community in the WTO, the Court recalled two provisions of the WTO Agreement which expressly refer to it: Article IX[239] which refers to the decision-making process and Article XI (1)[240] which allows acceptance by "contracting parties to GATT 1947 and the European Communities, which are eligible to become original members of the WTO."

The conclusion of the Court was that while the competence to conclude GATT 94' fell under Article 113[241] TEC, the limited scope of such provision and of other implied powers led to the conclusion that GATS[242] and TRIPs[243] could only be concluded by the EC together with the Member States as they were jointly competent in these fields[244] . It was reluctant to recognize the exclusive competence of the Community in

[237] See note 245, p. 245
[238] Opinion 1/94 of the Court of Justice, 1994 E.C.R. 1-5267
[239] Article IX WTO Agreement "...Where the European Communities exercise their right to vote, they shall have a number of votes equal to the number of their member States which are Members of the WTO"
[240] Article XI (1) WTO Agreement "'The contracting parties to GATT 1947 as of the date of entry into force of this Agreement and the European Communities which accept this Agreement and the Multilateral Trade Agreements…shall become original Members of the WTO"
[241] Now Article 207 TFEU, which deals with the Common Commercial Policy (CCP)
[242] The Court referred to the distinction of four modes of the supply of services in the relevant Agreement, from which only cross-frontier supplies being 'not unlike trade in goods' fall within the scope of Article 113 ECT
[243] The Court found that rules on intellectual property affect trade, but the TRIPS Agreement does not relate only to international trade.
[244] Under Article 113 ECT also the SPS Agreement, the Agricultural Agreement and the TBT Agreement were included

areas which involve the free movement of persons or have not been subject to intra-Community harmonization yet[245].

Therefore, in 1995 both the Community and the Member States became part of the WTO, as original members. For some observers, such opinion was a missed opportunity to recognize the Community as sole voice of the Member States across the whole spectrum of international trade.[246] The need to extend the Common Commercial Policy also in the sector of services and intellectual property has been addressed in the following years, thanks to the Amsterdam Treaty[247] first and the Nice Treaty[248] then. In the end, the Lisbon treaty re-included these two sectors in the exclusive competence of the EU as defined in Article 207 TFEU[249].

[245] *WTO-Agreement* in *Columbia Journal of European Law*, Vol. 1, Issue 2 1995, p. 353
[246] BOURGEOIS J. H. J. *The EC in the WTO and Advisory Opinion 1/94: An Echternach Procession*, in *Common market Law Review*, 1995, p.104
[247] Article 133 par. 5 TEC
[248] Article 133 par. 5-6 TEC providing for a mixed competence
[249]Article 207 par. 1 "The common commercial policy shall be based on uniform principles, particularly with regard to changes in tariff rates, the conclusion of tariff and trade agreements relating to trade in goods and services, and the commercial aspects of intellectual property, foreign direct investment, the achievement of uniformity in measures of liberalisation, export policy and measures to protect trade such as those to be taken in the event of dumping or subsidies…"

1.3.2 The protection of non-trade values in the WTO system- from Article XX GATT to the SPS and TBT Agreements

Even though this "world trade system" does not achieve the high level of integration reached in the EU, the establishment of the WTO contributed to make these two systems closer. First, the WTO differently from GATT 47', deals not only with goods but also services and intellectual property. Second, the free movement of goods is legally shaped by provisions similar to those provided in the EU legal system: Article XI[250] set forth a "general elimination of quantitative restrictions" as well as Article 34 TFEU and Article XX[251], whose function can be compared to Article 36 TFEU, provides for an exhaustive list of "general exceptions". Moreover, the Agreement on the Application of sanitary and phytosanitary measures (SPS agreement) and the Agreement on technical barriers to trade (TBT agreement) are the most relevant WTO agreement in the area of food law[252].

In fact, the globalization of economic activities, the on-going scientific developments, new transportation technologies and the integration of markets achieved in the context of the WTO, may cause serious challenges for regional and global food security[253]. The rationale is that whatever is the free-trade system concerned, a proper balance between economic interests and social values must be done[254]. International trade increases global health, it allows "*countries to specialize in the production of goods in which*

[250]Article XI par.1 "No prohibitions or restrictions other than duties, taxes or other charges, whether made effective through quotas, import or export licences or other measures, shall be instituted or maintained by any contracting party on the importation of any product of the territory of any other contracting party or on the exportation or sale for export of any product destined for the territory of any other contracting party"

[251] Article XX par.1 "Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures: (a) necessary to protect public morals; (b) necessary to protect human, animal or plant life or health" and others.

[252] See note 251 p.89

[253] CHING-FU L., *The WHO in Global Food Safety Governance: A Preliminary Mapping of Its Normative Capacities and Activities* in *International Food Law and Policy*, 2016, p.1

[254] For a general overview on the matter see NICHOLS P. M., *Trade without values*, in *Northwestern University Law Review*, vol 90, n 2, 1996 p. 657-719

they have a comparative advantage and import those goods in which they do not"[255]. Trading is itself beneficial, since it promotes cooperation and the interconnection of interests and this is why countries "*which trade with each other are less likely to go to war than are countries that erect trade barriers*"[256]. On the other hand, social values (such as environmental protection, animal welfare, human health) may conflict with the imperatives of free trade and since non-trade values change as time passes, such conflicts may be potentially infinite.

This circumstance, in the WTO system, has been addressed by the jurisprudence of the WTO panels and of the Appellate Body, which have often relied on Article XX GATT to include non-economic interest in trade disputes.[257] This provision, in fact, allows WTO members to pursue national non-trade policies to the detriment of the market ideal. As the Appellate Body reported in the *US-gasoline* case[258], the list of general exceptions included in Article XX is exhaustive and a non-trade value may enjoy protection only as far as it can be subsumed under this provision[259].

Differently, Article 2.2 of the TBT Agreement provides for an open-ended list of legitimate objectives; yet, whenever the alleged ground for adopting a certain measure is not enlisted, it must be anyway "lawful, justifiable or proper"[260](i.e. one of those legitimate objectives mentioned in other WTO treaties). Moreover, the formulation of Article 2.2 makes clear that (as in the EU) not only discriminatory measures, but also

[255] SYKES A. O., *Countervailing Duty Law: An Economic Prospective*, in *Columbia Law Review*, 1989, p. 17

[256] MCGEE R., *An economic analysis of Protectionism in the United States with implications for Interational Trade in Europe*, in *Washington Journal of International Law and Economy*, 1993, p. 551

[257] ANDERSEN H., *Protection of Non-Trade Values in WTO Appellate Body Jurisprudence: Exceptions, Economic Arguments, and Eluding Questions* in *Journal of International Economic Law*, 2015, p. 383

[258] WTO Appellate Body Report- United States - Standards for Reformulated and Conventional Gasoline (*US-Gasoline)*, WT/DS2/AB/R, adopted 20 May 1996, p. 22

[259] Only on rare occasions the Appellate Body recalled other sources of international law to protect non-trade values. See WTO Appellate Body Report, European Communities - Measures Affecting Asbestos and Products Containing Asbestos (EC-Asbestos), WT/DS135/AB/R and WTO Appellate Body Report, United States - Import Prohibition of Certain Shrimp and Shrimp Products (US-Shrimps), WT/DS58/AB/RW

[260] WTO Appellate Body Report, United States - Certain Country of Origin Labelling (COOL) Requirements (US-COOL), WT/DS384/AB/R and WT/DS386/AB/R, adopted 23 July 2012, par. 370

indistinctly applicable ones fall under the scope of this Agreement. In fact, technical barriers are legitimate as far as they have not been "prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade"[261]

Some other parallels with the EU system shall be noted[262]: as in the EU "mandatory requirements" have been created by the ECJ, in the WTO system these "legitimate objectives" go further than those established in Article XX GATT. Second, in both systems, discriminatory measures can be justified only by relying on Article 36 TFEU and Article XX GATT, which provide for exhaustive lists of justifications. Moreover Article 2.7 TBT Agreement provides that "Members shall give positive consideration to accepting as equivalent technical regulations of other Members, even if these regulations differ from their own, provided they are satisfied that these regulations adequately fulfil the objectives of their own regulations".

This provision encourages mutual recognition in the WTO system. Definitely, it cannot be compared *tout court* to the European one, since it has not yet achieved the importance it has in the EU. On the other hand, Article 6.3 TBT Agreement calls upon WTO members "to enter into negotiations for the conclusion of agreements for the mutual recognition of results of each other's conformity assessment procedures". As Beyon remarks, "The EC has relied on the encouragement of such agreements to extend its mutual recognition activity from the internal sphere to its trade relations with third countries"[263].

While the TBT agreement permits to apply technical regulations concerning the product itself or its making process as well as labelling, packaging, terminology etc[264], the SPS Agreement recognizes to its parties the "right to take sanitary and

[261] Article 2 par. 2 TBT Agreement
[262] PERISIN T., *Balancing Sovereignty with the Free Movement of Goods in the EU and the WTO - Non-Pecuniary Restrictions on the Free Movement of Goods* in *Croatian Yearbook of European Law & Policy*, Vol. 1, p.136
[263] BEYON P., *Community mutual recognition agreements, technical barriers to trade and the WTO's most favoured nation principle*, in *European Law Review*, 2003, p. 233
[264] In 1979 it was called the "Standard Code" and it dealt with all technical barriers, including measures which now fall under the SPS Agreement. When the WTO was created it was integrated into the 'single undertaking'.

phytosanitary measures necessary for the protection of human, animal or plant life or health"[265].

Therefore, for what concerns food safety issues, the SPS Agreement is more relevant than the TBT Agreement. The decision to negotiate such agreement during the 1986-1994 multilateral trade negotiations "marked a turning point in the development of multilateral trade rules and gave prominence to issues related to agricultural trade and the risk of importing invasive pests and diseases and food-borne illnesses"[266].

Typical SPS measures, in fact, concerns food safety requirements. Therefore, a measure concerning human health but not food safety or animal or plant-borne diseases will not be covered by this Agreement but may fall under the TBT Agreement[267]. It means that the latter is subsidiary to the SPS Agreement. Moreover, as already said, the purposes listed in the TBT Agreement does not concern only the protection of human health, but also other objectives, such as, inter alia, to prevent deceptive practices. So, differently from sanitary and phytosanitary measures, justifications adopted under the TBT agreement can also be based on technological or geographical reasons, rather than on scientific considerations[268].

Notwithstanding this difference, the TBT and the SPS Agreements have some aspects in common. First, also the latter was designed to address discriminatory as well as other disguised restrictions to trade. Second, also Article 4[269] SPS Agreement encourages mutual recognition of SPS measures. Moreover, the tool used by the present Agreement to reconcile the need to ensure free trade and non-economic values is encouraging

[265] Art. 2 par 1 SPS Agreement
[266] EVANS E. A., *Understanding the WTO Sanitary and Phytosanitary Agreement*, Institute of Food and Agricultural Sciences, available at http://edis.ifas.ufl.edu,. p. 7
[267] SCHEBESTA H., *International food law*, in VAN DER MEULEN B., VAN DER MEULEN M. (eds.) *EU Food Law Handbook*, Wageningen, 2014, p. 90
[268] See note 281
[269] Article 4 par.1 ". Members shall accept the sanitary or phytosanitary measures of other Members as equivalent, even if these measures differ from their own or from those used by other Members trading in the same product, if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of sanitary or phytosanitary protection. For this purpose, reasonable access shall be given, upon request, to the importing Member for inspection, testing and other relevant procedures"

harmonization through international standards as set forth in Article 3[270]. These standards are those elaborated by the so-called "three sisters of the SPS Agreement"[271] and for what concerns food safety standards they can mainly be found in the Codex Alimentarius. In order to prevent disguised protective measures, Article 2 SPS lays down the conditions that a sanitary or phytosanitary measure must met in order to be lawful: necessary, proportionate, based on scientific principles and evidences, nor discriminatory neither a disguised restriction on international trade. As far as these conditions are fulfilled "sanitary or phytosanitary measures shall be presumed to be in accordance with the obligations of the Members under the provisions of GATT 1994 which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b)"[272].

SPS measures, must be based on scientific assessment of the risk, but "*in cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information*…"[273]. For some authors this provision, probably "stood as a model for the wording"[274] of the precautionary principle in Article 7 of the General Food Law. Moreover, the first case concerning the SPS Agreement was the *Hormones* case between the EC and United States and Canada.

As will be discussed in the next chapter, this case is "from the angle of the precautionary principle one of the most interesting WTO cases"[275]. This is because, the level of risk that different societies can tolerate is not universal, and this assumption

[270] Article 3 par.1 "To harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist…"
[271] The Codex Alimentarius Commission, the International Office of Epizootics, and the Secretariat of the International Plant Protection Convention.
[272] Article 2. par. 4 SPS Agreement
[273] Article 5.7 SPS Agreement
[274] See note 282, p. 91
[275] VEINLA H., *Free Trade and the Precautionary Principle* in *Juridica International*, Vol. 8, 2003 p. 188

may lead to varying approaches and responses to risk assessment[276]. It also sheds a light on the fact that food safety, has often played and still plays an increasingly important role in trading relations. The existing multilateral rules embodied in the SPS Agreement, in fact, are more and more being supplemented through a series of bilateral and multilateral agreements[277] and the EU Free trade Agreements are a clear example of this tendency.

1.3.3 International trade dimension of food law: the shift from multilateralism to bilateralism

As it has been analyzed, the variety and complexity of these non-tariff barriers has always represented a big challenge to WTO law. Yet, bilateral and regional approaches to this phenomenon are of manifest importance[278] too. This parahraph, in fact, will address the failure of multilateral negotiations in the framework of the WTO and the current tendence towards bilateralism that almost all States has shown. This preference is more and more evidenced by the increasing role that Regional Trade Agreements, also known as Free Trade Agreements[279] have acquired in the context of global trade.

By common definition, free trade agreements (FTAs) are "*legally binding arrangements between two or more countries, which while providing reciprocal preferential treatment in trade, allows each member to keep its own tariff structure in trade with third countries*." [280]

[276] REID E., *Risk Assessment, Science and Deliberation: Managing Regulatory Diversity under the SPS Agreement* in *European Journal of Risk Regulation*, Vol. 3, Issue 4, 2012, p. 536
[277] WAGNER M., *The Future of SPS Governance: SPS-Plus or SPS-Minus*, in *Journal of World Trade, (*2017*)*, p.445
[278] TERCHETE J.P., *Non-tariff barriers to trade*, in *Max Planck Encyclopedia of Public International Law*, 2014, p.8
[279] For some scholars this definition underlines the positive effects on these agreements and not also their discriminatory nature. See LESTER S., MERCURIO B., BARTELS L., *Bilateral and Regional Trade Agreements. Commentary and analysis*, Cambrige University Press, Cambrige, 2015
[280] These Agreements are also called "Regional Trade Agreements". The difference is that he term "Free Trade Agreements" doesn't include customs unions. Another term often used is "Preferential Trade Agreements" which does not include geographical references. See supra, note 279, p. 5

The legal basis to create customs unions and free-trade areas is set forth in Article XXIV GATT 94', which provides for an exception to the most favoured nation clause[281]. The WTO Committee on Regional Trade Agreements (CRTA), is assigned with the task of verifying the WTO compliance of preferential trade agreements notified under GATT Article XXIV and GATS Article V. Initially, the progress of trade liberalisation under the preferential trade groupings was relatively slow, but since the middle of the 1990s it has been particularly intensive.

While in 1995 the number of ratifications filed with the WTO concerning regional trade agreements amounted to 126, by April 2015 their number has grown up to 612, among which 416 already in force[282]. These data make evident that "*FTAs have become a crucial component of the international trading system, since today more than half of the world trade occurs through FTAs*"[283].

The proliferation of bilateral and regional relations to the detriment of the WTO lies in the lack of progress in multilateral negotiations. In particular, when negotiations in the GATT framework have shown their results in reducing customs tariff, Contracting parties started to focus on other types of trade barriers (i.e. anti-dumping measures, non-tariff measures, intellectual property rights and so on)[284].

Yet, "*the expectation of shaping a multilateral trade system based on the WTO rules has become blurred as the Doha Round could not be concluded and has been in a*

[281] Article I par.1 GATT 94' "With respect to customs duties and charges of any kind imposed on or in connection with importation or exportation or imposed on the international transfer of payments for imports or exports, and with respect to the method of levying such duties and charges, and with respect to all rules and formalities in connection with importation and exportation, and with respect to all matters referred to in paragraphs 2 and 4 of Article III,* any advantage, favour, privilege or immunity granted by any contracting party to any product originating in or destined for any other country shall be accorded immediately and unconditionally to the like product originating in or destined for the territories of all other contracting parties"

[282] TANGERMANN S., *Agriculture and Food Security: New Challenges and Options for International Policy*, E15 Expert group on Agriculture, Trade and Food Security-Policy Options Paper, E15 Initiative, World Economic Forum, 2016

[283] MASHAYEKHI M. et al. *Multilateralism and Regionalism*, in *Multilateralism and Regionalism: The New Interface*, UNCTAD, New York, p. 3

[284] JENSEN M. F., GIBBON P., *Africa and the WTO Doha Round: An Overview*, in *Development Policy Review*, Vol. 25, p.6

deadlock"[285]. Differently from the Uruguay Round, the Doha Round[286] brought "development" into the fore, along with the idea to create a more equitable trading system. This is the reason why it was said that "*the failure of the DDA will be regarded as a missed historic opportunity to eliminate export subsidies and to put an end to trade distortion*"[287].

Yet, the slow progress in the DDR is due also to the single undertaking approach, thereby "nothing is agreed upon until everything is agreed upon"[288]. It is true that the increase of the number of WTO members has made negotiations more and more complex, but one of the main obstacles lies more on the feeling of dissatisfaction of the developing countries with the current and past functioning of the WTO system. In fact, the process of trade liberalisation undertaken since the GATT 47' has always aimed to ensure the interests of the developed countries[289].

Therefore, while economic sectors in which they had comparative advantages have been liberalised, in the others protective measures have been upheld. An example is trade in agricultural products, one of the most sensitive matters from a social and economic point of view. During the Doha Round, in fact, agricultural negotiations determined a division among WTO members: on the one hand, developing countries seeking a significant reduction of agricultural subsidies and changes in tariff policies provided by developed countries, on the other hand, the latter trying to maintain a wide protection of their own agricultural production. In this regard, the global financial and economic crisis has played a key role in favouring protectionist tools (such as "buy

[285] TEKÇE M., ACAR S., *From multilateralism to bilateralism: the evolution of global trade policies,* in *YIL*, 2008, p.106
[286] In November 2001, WTO member governments initiated new negotiations at the Fourth Ministerial Conference in Doha, (Qatar). This new initiative was called the Doha Development Agenda (DDA). Subsequent ministerial meetings took place in Cancún (2003), and Hong Kong (2005). Related negotiations took place in Paris (2005), Potsdam (2007), and Geneva (2004, 2006, 2008), Nairobi (2015)
[287]LEAL-ARCAS R., *The Death of the Doha Round. What Next for Services Trade?, Legal Series Working Paper*, no. 1760, 2006, p. 14
[288] WOLFE R., *The WTO single undertaking as negotiating technique and constitutive metaphor*, in *Journal of International Economic Law*, Vol. 12, Issue 4, p. 836
[289] JONES K., *Green room politics and the WTO's crisis of representation*, in *Progress in Development Studies* Vol. 9, No. 4, p. 349

national" campaigns) to the detriment of free market policies[290]. Owing to disagreements concerning not only agriculture, but also non-tariff barriers, services and other issues, in 2008 negotiations stalled and since this breakdown, even though repeated attempts to revive the talks have been undertaken, they do not have produced successful outcomes so far[291].

The deadlock of the multilateralist process, has changed worldwide the trade policies. Many states, dissatisfied with the course of the Doha Development Round negotiations, have expressed the idea that limiting the number of parties would ensure a greater progress in the liberalisation of trade under regional or bilateral negotiations and significantly shortens the period of negotiations, translating them into a higher number of such agreements.[292]

According to Bhagwati's analysis, a "third wave of regionalism"[293] reached its height with the suspension of the Doha negotiations. Such wave has three main features: first, contrary to the previous trend of regionalism[294] economic distance no longer matters, since FTAs are not restricted to countries with geographic and economic proximity. Second, new generation FTAs go beyond trade liberalization and include also "deep integration" measures (standards, sanitary measures, services trade, foreign investment, intellectual property and regulatory regimes). Third, the new FTAs covers more areas, while having a smaller membership, differently from the previous FTAs, which used to be characterized by "*narrowness in issue coverage but broadness in*

[290] BUSSIERE M., PEREZ-BARRIERO E., STRAUB R., TAGLIONI D., *Protectionist responses to the crisis: Global trends and implications*, in *The World Economy*, Vol. 34, p. 840
[291] DEL VECCHIO M., DI COMITE V., *Da Doha a Bali il futuro dell'OMC tra nuove speranze e antiche questioni*, in *La Comunità Internazionale*, 2014, p. 387 e ss.
[292] WR0BEL A., *Multilateralism or bilateralism: the EU trade policy in the age of the WTO crisis*, in *EKONOMIKA*, 2013, p. 7
[293] BHAGWATI J., *U.S. Trade Policy: The Infatuation with Free Trade Agreements* in, *The Dangerous Drift to Preferential Trade Agreements*, AEI Press, Washington DC, 1995. Bhagwati dates the second wave of regionalism between 1980s and 1990s, while "the first wave of regionalism that took place in the 1960s failed to spread because the US supported a multilateral approach" in *Regionalism and Multilateralism: An Overview* in *New Dimensions in Regional Integration*, Cambridge University Press, Cambridge, p. 28
[294] E.g. EFTA, NAFTA, MERCOSUR

terms of membership"[295]. Furthermore, the more FTAs are concluded, the more they tend to go beyond the WTO borders.

In this regard, it has been distinguished among "WTO+" provisions, meaning FTAs rules regulating a certain sector differently from the WTO Agreements and "WTO x" provisions, meaning those rules legally shaping sectors not covered under the WTO system[296]. This is why free trade agreements are usually considered as "game changers"[297] whenever agreement upon a certain sector cannot be reached in the multilateral forum.

On the average, there are 13 preferential agreements per one member of the WTO[298]. Moreover, also the rationale at the core of bilateral or regional agreements have gradually changed. At the beginning, it was all about exchanging access to the market through reducing customs tariffs. Nowadays, the main goal is to reduce non-tariff barriers by harmonizing different national rules, making a shift from "trade liberalization" to "trade regulation"[299]. In fact, as the World Trade Report 2011 explains "*These tendencies are a clear reflection of the growing integration of the world economy and the "internationalization" of policies that were once considered domestic*"[300].

For what concernes the food sector the main reason behind the proliferation of these agreements lies in their capacity, at least in theory, to handle certain sensitive issues such as food security and consumer protection in a more effective way than multilateral

[295]RAIAN R., SEN R., *The New Wave of FTAs in Asia: Implications for ASEAN, China and India*, in *Asian Economic Cooperation and Integration: Progress, Prospects, and Challenges*, 2005 p.127
[296] HORN H., MAVROIDIS P. C., SAPIR A, Beyond the WTO? An anatomy of EU and US preferential trade agreements, Volume II, Bruegel Blueprint Series, Belgium, 2009
[297] ALABRESE M., *TTIP e agroalimentare. Prime riflessioni a margine delle proposte dell'Unione Europea nella negoziazione della "Trans-Atlantic trade and investment partnership* in *Rivista di diritto agrario*, 2016, fasc. 2, pt. 1, p. 214
[298] WTO (2011). World Trade Report 2011. *The WTO and preferential trade agreements: From coexistence to coherence*. Geneva: World Trade Organization, p. 47
[299] COTTIER T., *International Economic Law in Transition from Trade Liberalization to Trade Regulation*, in *Journal of International Economic Law*, 2014, p. 673
[300] See note 313 p. 5

agreements[301]. This assumption is even more true considering that, as already said, one of the main aims of FTAs is the "regulatory convergence", which can only be achieved through "presumptive mutual recognition, voluntary recognition of equivalence, some form of regulatory cooperation or a combination of these approaches"[302]. Food law, in fact, is perhaps one the legal sectors in which non-tariff barriers and different standards are more likely to be used as disguised protectionism and therefore, the rationale of these free trade agreements is to create an international legal system providing for common rules which while protecting consumers, ensures free trade.

This need has become more and more relevant owing to the increasing phenomenon of the "global value chain", meaning the "unbundling of stages of production across borders"[303]. The so-called value chains have two main consequences: on the one hand, different standards represent additional costs for producers, on the other, both consumers and States are aware of the risks for human health that food products coming from a big chain of distribution may cause. Therefore, the proliferation of regional and bilateral agreements may fill the gap between different legal systems, through a deep integration of standards[304].

The European Commission too, underlines that nowadays the main obstacles to trade are not customs tariffs but the so-called "behind the border"[305] obstacles to trade (i.e. food safety and environmental standards). When it comes to the EU trade policy it must be reminded that "*the European Union is party to more FTAs than any other economy in the global trading system*"[306]. The Commission Communication "Global Europe"[307]

---

[301] ALABRESE M., *Gli accordi commerciali mega-regionali e l'elaborazione del diritto agroalimentare* in *Rivista di diritto agrario,* fasc. 1, 2017, pt.1 p. 138

[302] BERGKAMP L., KOGAN L., *Trade, the Precautionary Principle and Post-Modern Regulatory Process*, in *European Journal Risk Regulation*, 2013, p. 493

[303] BALDWIN R., Global supply chains: why they emerged, why they matter, and where they are going, in Global value chains in a changing world, WTO Publications, 2013, p. 13

[304] See note 316 p. 111

[305] DG trade, available at http://trade.ec.europa.eu/doclib/press/index.cfm?id=869

[306] Business Roundtable, 2007, *We Can't Stand Still: The Race for International Competitiveness*, Business Roundtable White Paper, Washington DC

[307] European Commission, 2006, *Global Europe: Competing in the World*, Commission Staff Working Document, Directorate General of External Trade COM (2006) 567, 4 October 2006

is crucial in this regard, since it has marked a shift from multilateralism to bilateralism of the Common Commercial Policy[308]. The purpose of that Communication was "*to set out the contribution of trade policy to stimulating growth and creating jobs in Europe...to ensure that Europe remains open to the world and other markets open to us*"[309].

With regard to the Free Trade Agreements (FTAs), the Commission underlines how they can be able "*to go further and faster in promoting openness and integration, by tackling issues which are not ready for multilateral discussion… many key issues including investment, public procurement, competition, other regulatory issues and IPR enforcement, which remain outside the WTO, at this time can be addressed through FTAs*". The next chapter will address the main challenges and opportunities that the new EU FTAs agreements, negotiated and concluded in the light of this new trade strategy may represent for the European food security.

[308] ALABRESE M., *TTIP e agroalimentare. Prime riflessioni a margine delle proposte dell'Unione Europea nella negoziazione della "Trans-Atlantic trade and investment partnership* in *Rivista di diritto agrario,* 2016, fasc. 2, pt. 1, p. 215
[309] See note 322 p.1

Chapter 2)

The new generation of EU Free Trade Agreements: challenges and opportunities for the strict European food safety standards

Preliminary remarks

The Commission communication "Global Europe" has oriented the European trade policy from multilateral trade towards a new generation of Free Trade Agreements[310], including the EU-Korea Free Trade Agreement (KOREU) entered into force in 2015, the EU-Singapore Free Trade Agreement (EUSFTA) and the EU-Vietnam Free Trade Agreement (EUVFTA) whose negotiations have been finalised respectively in 2014[311] and in 2015[312]. Yet, when it comes to food security issues, the most debated new FTAs have been the EU-USA trade deal, TTIP (Transatlantic Trade and Investment Partnership), and the so-called CETA (Comprehensive Economic and Trade Agreement) between EU and Canada.

These "mega-regionals" are deep integration partnerships between States or regions which are leaders of global trade. They represent an opportunity to expand regional trade and to ensure regulatory compatibility, by reducing non-tariff barriers and market-distorting obstacles.

Yet, the EU FTAs concluded so far are shaped differently for what concerns the free trade of food. While agreements with acceding States or EU associated States partially incorporate "*the acquis communautaire on food and agricultural products*"[313], with

[310] AHEARN R. J., *Europe New Trade Agenda*, Congressional Research Service Report No. RS22547, p.1

[311] Negotiations on goods and services were completed in 2012, while those on investment protection on the 17 October 2014.

[312] The text of the EU-Vietnam free trade agreement was published in 2016, following the announcement of the conclusion of the negotiations in 2015. The legal review of the negotiated-text is currently on-going and will be followed by translation into the EU's official languages and Vietnamese. The Commission will then present a proposal to the Council of Ministers for approval of the agreement and ratification by the European; more information are available at http://ec.europa.eu/trade/policy/countries-and-regions/countries/vietnam/

[313] SCHROEDER W., *Transatlantic Free Trade agreements and European Food standards*, in *European food and feed Law Review*, 2016, p. 494

non-associated third countries, such as Canada, US, Vietnam and Singapore the FTAs provisions point to the incorporation of the WTO rules described in chapter 1 (i.e. TBT and SPS Agreements).

Yet, even if there is a great economic potential by dismantling trade barriers in the food sector, all over Europe concerns have been expressed about the fact that these agreements are likely to pose European food and agriculture standards under threat. The rationale of these claims lies in the significant differences in the food systems, existing between EU on the one hand and USA and Canada on the other.

The *Hormones* case decided by the WTO Appellate Body in the 1980' and the different approaches when it comes to risk assessment and application of the precautionary principle are clear examples of this gap. Therefore, the fear is that regulatory cooperation may lead food safety standards to the lowest common denominator, allowing unsafe food to enter the European market. Moreover, with regard to disputes between States and investors, the dispute settlement mechanism provided in these FTAs has raised fears in the public opinion. It would allow private companies to challenge domestic laws which, aimed at protecting public goods (such as public health and food security standards) restrict trade.

While TTIP negotiations were halted indefinitely following the 2016 U.S. presidential election, substantial parts of CETA, provisionally apply from September 2017, until its formal entry into force. The focus of this chapter will then shift on the other side of the word, analysing the FTAs negotiated by the EU with Southeast Asian countries, in particular Singapore and Vietnam. Albeit these deals are not problematic from the point of view of food security, their relevance from an economic prospective is undeniable, since these countries are among the major trading partners in light of the EU's new trade strategy.

This Chapter is divided into three parts addressing respectively the TTIP, CETA and the Free Trade Agreements concluded with Vietnam and Singapore. The first paragraph will deal with the public debate raised during TTIP negotiations and will try

to understand the rationale of the anti-TTIP movements undertaken all over Europe. The second one will address the critical issues existing between EU and Canada when it comes to the regulation of the food sector and will seek to explain how the CETA's trade-facilitating tools to overcome legislative divergences. The third paragraph will explain the economic potential which the Asian market represents for the European food products and the impact of the ECJ advisory opinion 2/15 on the Common Commercial Policy.

2.1 Transatlantic Trade and Investment Partnership (TTIP)

2.1.1 The lack of transparency of the TTIP negotiations and the public debate after the TTIP leaks

TTIP is one of the so called "mega-regionals" agreements. They are described as "*deep integration partnerships between countries or regions with a major share of world trade and foreign direct investment (FDI), in which two or more of the parties are in a paramount driver position in global value chains. Beyond market access, emphasis in this integration is on the quest for regulatory compatibility and a rules basket aimed at ironing out differences in investment and business climates*"[314]. Negotiations for the TTIP agreement were officially launched on February 2013[315] with the aim of enhancing the transatlantic economic relationship, advancing trade and investment liberalization.

Karel De Gucht**,** European Commissioner for Trade, described this deal as "the biggest bilateral trade negotiation ever undertaken, a game changer not only for our future bilateral trade and investment but also for the development of global rules"'[316]. The

[314] See, inter alia, MELENDEZ-ORTIZ R., *Mega-regionals. What is going on?* In *Mega.regional Trade Agreeents. Game changers or costly distractions for the World Trading system?*, 2014, p.6

[315] EUROPEAN COMMISSION, *Statement from United States President Barack Obama, European Council President Herman Van Rompuy and European Commission President José Manuel Barroso,* Brussels/Washington, 13 February 2013, available at http://europa.eu/rapid/press-release_MEMO-13-94_en.htm

[316] Karel De Gucht, European Trade Commissioner, Transatlantic Trade and Investment Partnership: Opening Free Trade Negotiations with the United States, Speech Before the Committee on International

Centre for Economic Policy Research (CEPR)[317] has conducted an economic analysis of the potential effects that TTIP may produce, if successful. It has predicted that the deal "would increase the size of the EU economy around €120 billion and the US by €95 billion and this would be a permanent increase in the amount of wealth that the European and American economies can produce every year"[318]. Moreover, this agreement would create the largest free trade area of the world[319].

The TTIP has 24 chapters, grouped into four parts: market access, regulatory cooperation, trade rules addressing shared global changes and institutional rules. The second part comprises a horizontal chapter, dealing on the one hand with technical barriers to trade (TBTs) and on the other with food safety and animal/plant health. Rules concerning specific industries are addressed[320] too. Of the three parts, "regulatory convergence offers by far the greatest potential for substantial and lasting benefits"[321]. This deal in fact, like other FTAs of new generation, pursue the removal of tariffs and the opening of the markets to liberalize the field of services, investments and public procurement.

Yet, it represents mainly an opportunity for reaching harmonization and convergence of standards[322]. In fact, since tariffs on trade between the EU and U.S. are already low, the focus of the negotiating mandate has shift towards the so-called "*behind the border obstacles to trade*", that result, for instance, from differences in consumer safety and

Trade (INTA) of the European Parliament/Brussels, 21 February 2013, available at http://europa.eu/rapid/press-release_SPEECH-13-147_en.htm

[317] CEPR is a leading independent pan-European economic research organization

[318] European Commission, Centre for Economic Policy Research, Transatlantic Trade and Investment Partnership: The Economic Analysis Explained, September 2013, p.2

[319] MICHAEL B.G. FROMAN, 2014 Trade policy agenda and 2013 annual report of the president of the United States on trade agreements program 138 (2014), available at https://ustr.gov/sites/default/files/201

[320] Cosmetics, Engineering products, Chemicals, Information and communication technologies (ICT), Medical devices, Pesticides, Pharmaceuticals, Textiles, Vehicles

[321] BERGKAMP L., KOGAN L., *Trade, the Precautionary Principle and Post-Modern Regulatory Process*, in *European Journal Risk Regulation*, 2013, p. 493

[322] "Regulatory harmonization and regulatory compatibility are flip sides of the same coin. Regulatory convergence is the rate at which harmonization is achieved. Regulatory cooperation is a process aimed at achieving convergence", see note 9, p. 494

food standards[323]. Moreover, in order to promote compatibility of regulations, TTIP provides for the first time in a trade agreement[324], the so-called "Good regulatory practices" including transparency, early warnings, stakeholder consultation and impact assessment. Therefore, as the DG Trade underlines "working together on regulations could cut costs, while upholding the EU's strict levels of protection for people and the environment"[325]. Furthermore, the Commission has estimated that between "two thirds of the gains from a future agreement would come from cutting red tape and having more coordination between regulators"[326]

Yet, when it comes to non-tariff barriers, negotiations concerning Sanitary and Phytosanitary measures (SPS plus) and Technical Barriers to Trade (TBT plus), build on the key principles of the two WTO SPS and TBT Agreements, are expected to be ambitious in scope[327]. This is mainly due to the "transatlantic regulatory divide"[328] existing between EU and U.S. Moreover, the commitment to pursue regulatory convergence will not end once the Agreement will be signed, but even after its ratification the parties' representatives shall keep on discuss legislative initiatives in the responsible body.

Scholars, in fact, define TTIP as a "living agreement", since "*the EU and the US are not limiting themselves to concluding a traditional FTA plus, by agreeing on some additional, procedural requirements. They are rather striving to come up with a new model of economic integration based on a permanent bilateral regulatory cooperation*

[323] The existence of different regulations represents additional costs in which companies incur while trading across the two markets

[324] Good regulatory practices appear also in the Comprehensive Economic and Trade Agreement (CETA) between the EU and Canada, yet TTIP is the first one that ensure their respect through an enforcement mechanism.

[325] DG Trade, The Transatlantic Trade and Investment Partnership (TTIP)Towards an EU–US trade deal: Inside TTIP, 2015, p.6

[326] European Commission, The Transatlantic Trade and Investment Partnership: The Regulatory Part, September 2013, p.2

[327] *Member States endorse EU-US trade and investment negotiations*, European Commission, 4 June 2013, http://trade.ec.europa.eu/doclib/press/index.cfm?id=918

[328] This divide results in diverging regulations and standards, duplicative testing requirements, diverging conformity procedures and different documentation requirements See note 9, p. 496

mechanism through horizontal provisions complemented by a number of specific commitments across sectors"[329].

Since its enhanced focus on regulatory cooperation would more than ever be about affecting domestic policies, the lack of transparency in the negotiations has been one of the main criticisms expressed by the civil society organizations (CSOs)[330] and legislators. It was not easy at all to ascertain exactly what was on the table of TTIP and concerns have been raised about the fact that there were too many issues on which the population had not been sufficiently informed. Obviously the less public scrutiny is at stake, the more mistrust and fears come to the fore. The DG Trade has justified the need to maintain the negotiating mandate as restricted document claiming that "it is necessary to protect EU interests and to keep chances for a satisfactory outcome high" because, "when entering into a game, no-one starts by revealing his entire strategy to his counterpart from the outset"[331].

Yet, owing to the increasing criticisms, the need to make trade policy more transparent and open to public scrutiny has grown so much to become one of the pillars of the Communication 'Trade for all'[332], which has marked a new trade strategy in 2015. The idea is to manage the EU trade policy to create global rules reflecting EU values and principles and to "ensure that economic growth goes hand in hand with social justice, respect for human rights, high labour and environmental standards, and health and safety protection"[333]. Therefore, this communication underlines that along with economic values, EU trade policy is mainly called to ensure the integration of EU

[329] ALEMANNO A., *The regulatory cooperation chapter of the Transatlantic Trade and Investment: Institutional structures and democratic consequences*, in *Journal of International Economic Law*, 2015, p.7
[330] DE VILLE F., E SILES-BRUGGE G., TTIP: *The truth about the Transatlantic Trade and Investment Partnership*, Cambridge, Polity Press, 2015
[331] See note 326
[332] European Commission communication *Trade for all: Towards a more responsible trade and investment policy*, Brussels, October 2015, p. 18, available at http://ec.europa.eu/trade/policy
[333] Ibid. p. 22

political and social values in the global dimension of trade[334] and the EU-U.S. partnership is considered strategic and ambitious in this regard.

While strengthening Europe's relationship with the United States, the most important political ally and biggest export market, "it will provide an effective laboratory for global rules"[335]. Albeit some EC initiatives to provide greater access to documents relating to TTIP and information about meetings[336], criticism with regard to transparency has not withered away[337], rather has reached its height after the "TTIP leaks"[338] in 2016.

On May 2016, in fact, Greenpeace Netherlands has released about half of the draft text as of April 2016, prior to the start of the 13th round of TTIP. The documents represent a substantial part of the negotiating texts, 13 of 17 chapters believed to have reached the consolidation phase of negotiations. Greenpeace justified its leak with the need to facilitate a proper democratic debate about the texts, since "*the secrecy surrounding the negotiating process goes against the democratic principles of both the EU and the US*"[339].

Yet, after the disclosure of 248 pages of the secret texts, the main arguments put forward by NGOs and public opinion was that perhaps "the covert nature of the talks may well be the least of our problems"[340]. In fact, public debate on the ongoing negotiations focused on the fear that this Agreement could create a regime that places

---

[334] ALABRESE M., *TTIP e agroalimentare. Prime riflessioni a margine delle proposte dell'Unione Europea nella negoziazione della "Trans-Atlantic Trade and Investment Partnership* in *Rivista di diritto agrario*, 2016, fasc. 2, pt. 1, p. 217

[335] See note 332 p. 30

[336] COREMANS E. *From access to documents to consumption of information: The European Commission transparency policy for the TTIP negotiations*, in *Politics & Governance*, 2017, Volume 5, Issue 3, p. 29

[337] According to Greeneace, "even if some documents have been disclosed, they were frequently incomplete and out of date. Even members of the European Parliament had only limited access to in special reading rooms. Every negotiating round takes place behind closed doors and joint EU-US press conferences on TTIP are devoid of real content. Consultations with civil society and stakeholder meetings are little more than content-free formalities"

[338] GREENPEACE Netherlands "*TTIP Leaks*", 1 May 2016, available at https://trade-leaks.org/ttip/

[339] Ibid.

[340] WILLIAMS L., *What is TTIP? And six reasons why the answer should scare you*, available at https://www.independent.co.uk/

profit ahead of human and animal health, food safety and consumer protection. In particular, "*the potential impact of TTIP on EU food safety standards has attracted a lot of attention and no little anxiety*"[341].

Some opponents to the agreement argue that the result of the negotiations will be "to dismantle EU food safety regulations which amount to impediments to trade and profitmaking"[342]. To address all this criticism, Commissioner Malmstrom underlined that "*no EU trade agreement will ever lower our level of protection of consumers, or food safety, or of the environment. Trade agreements will not change our laws on GMOs, or how to produce safe beef, or how to protect the environment. Any EU trade deal can only change regulation by making it stronger*"[343].

However, consumers' fear that US export interests will lead to changes in EU food safety standards in understandable in light of two main considerations[344]. First, the objective to create a Transatlantic internal market, likewise the EU market, suggests that goods coming from U.S. will freely enter Europe and this "will require Europeans to import hormone-treated, chemically sanitized and genetically modified American foods"[345]. Second, labelling all regulatory differences as "non-tariff barriers" which shall be set aside to pursue economic gains is not helpful too[346]. Therefore, in order to

---

[341]MATTHEWS A., *Food safety regulation in TTIP: much ado about nothing*, in *European Journal of Risk Regulation*, Vol. 7, Issue 2, 2016, p. 256

[342] BARKER D., *Trade matters: Transatlantic Trade and Investment Partnership (TTIP)-Impacts on food and farming*, Center for Food Safety Report, *2014*

[343]MALSTROM C, *Negotiating TTIP*, 2 May 2016, available at https://ec.europa.eu/commission/commissioners/2014-2019/malmstrom/blog/negotiating-ttip_en

[344] See note 341, p. 257

[345]WATTS J., *The Transatlantic Trade and Investment Partnership: An Overly Ambitious Attempt to Harmonize Divergent Philosophies on Acceptable Risks in Food Production without Directly Addressing Areas of Disagreement* in *North Carolina Journal of International Law*, Vol. 41, Issue 1, 2015, p. 86

[346]European Commission, Centre for Economic Policy Research, *Transatlantic Trade and Investment Partnership: The Economic Analysis Explained*, September 2013, p. 10 After examining a list of existing regulatory barriers to transatlantic trade the researchers concluded that it was realistic to assume that 80 % of the cost reductions due to the removal of NTBs would benefit the US and the EU. BERDEN KOEN G., *Non-Tariff Measures in EU-US. Trade and Investment – An. Economic Analysis*. DG Trade OJ 2007/S 180-219493, 11 December 2009, available at http://trade.ec.europa.eu/doclib/docs/2009/december/tradoc_145613.pdf According to the report total elimination of actionable non-tariff barriers would boost EU GDP by 0.7 % per year, leading to an annual potential gain of $158 billion dollars; while US GDP by 0.3 % or $53 billion per year.

understand why harmonization of food regulation is "the most inflammatory issue in Europe's public discourse"[347] on the TTIP, it is necessary to analyse the different approaches existing in the EU and US systems when it comes to risk management and food security.

2.1.2 The regulatory principles in the European and American food security regulations

Even if it is not possible to say exactly how TTIP would affect EU food standards[348], anyway scholars claim that "TTIP seeks to resolve long-standing philosophical differences between European and American food policies"[349].

The German term "*Chlorhuhnchen*", which refers to the U.S. usage of chlorinated spray in processing chicken "*has become the rallying-call for Anti-TTIP activists*", a symbol of the alleged decline of European food safety standards[350]. On the other hand, opening agriculture markets will be a two-way street with benefits for both the EU and the US[351]: the latter is interested in selling more of its agricultural products (like wheat and soy), while EU has a clear interest in selling more of its high-quality foods to the US[352]. Moreover, by including the food and agricultural sectors in this Agreement, Parties seek to solve same points of contention already existing in their relations under

[347] FAIOLA A., *Free Trade with U.S.? Europe Balks at Chlorine Chicken, Hormone Beef*, in *Washington Post*, 5 December 2014
[348] Only the Commission's proposals are avaiable, but not the results of the negotiations
[349] See note 345 p. 87
[350] NUTTALL T., *Charlemagne: Ships that pass in the night*, in *THE ECONOMIST*, 13 December 2014
[351] European Commission, Faq on the EU-US Transatlantic trade and Investment Partnership (TTIP), 2013, p. 7 avaiable at http://trade.ec.europa.eu/doclib/docs/2013/may/tradoc_151351.pdf
[352] See note 350 "EU exports to the US are mostly higher value food products like spirits, wine, beer, and processed food (such as cheeses, ham and chocolate). At the moment some European food products, such as apples and various cheeses, are banned from the US market; others are subject to high US tariffs – meat 30%, drinks 22-23%, and dairy products up to 139%. Removing these and other barriers will help boost EU exports to the US.

the WTO, such as Genetically Modified Organisms (GMO), climatic changes, concentration on hormones in food etc.

In fact, over the last few years, American and European interests have conflicted many times in several human health and risk management issues. "The fact that the United States has not officially accepted the precautionary principle and has not recognized as a universal risk management tool has been one of the reasons for the disputes"[353]. In this regard, the European Commission, negotiating the TTIP on behalf of Member States, is promoting "SPS-plus" provisions that go far beyond those contained in the WTO SPS Agreement of 1995[354].

The 2016 consolidated text of the SPS Chapter[355] contains 22 articles and an introduction providing for the objectives to be achieved. The EU's textual proposal[356] includes, among the crucial purposes, the following: "*to facilitate trade between the Parties to the greatest extent possible while preserving each Party's right to protect human, animal or life and health in its territory*", "ensure that the Parties sanitary and phytosanitary measures do not create unnecessary barriers to trade" and "further the implementation of the WTO Agreement on the Application of Sanitary and Phytosanitary measures". Definitely, to ascertain whether or not a certain measure amounts to an "unnecessary" barrier is likely to become a source of controversy[357].

This is why resolving the issues surrounding the different understanding of the precautionary principle and the related regulatory differences would be the key to address food issues in the TTIP. The U.S, in fact has built its decision-making process on "*science-based risk assessment, cost-benefit analysis and is often seen as having a*

---

[353] VEINLA H., *Free Trade and the Precautionary Principle* in *Juridica International*, Vol. 8, 2003 p. 188

[354] WEISS M., MIDDLETON J., SCHRECKER T., *Warning: TTIP could be hazardous to your health* in *Journal of Public Health*, Volume 37, Issue 3, 1 September 2015, p. 367

[355] Avaiable at http://ec.europa.eu/trade/

[356] The Textual proposal is the European Union's initial proposal for legal text on" Sanitary and Phytosanitary Measures (SPS)" in TTIP. It was tabled for discussion with the US in the negotiating round of (29 September-3 October 2014) and made public on 7 January 2015.

[357] KOGAN A. L., *REACH and International Trade Law*, in *The European Union REACH Regulation for Chemicals*, Oxford, 2013, p. 309

strong risk-taking culture"[358]. In particular, the cost-benefit analysis, which assigns predetermined values to market factors and places crucial weight on economic benefits, is considered as the "foundational regulatory principle"[359] in the US. In the so-called *benzene case*[360] the U.S. Supreme Court made clear that "regulatory decisions cannot be made merely on an assumptive basis and therefore institutions are obliged to prove the existence of an essential hazard"[361].

The EU, on the other hand is considered more risk-averse and scientific uncertainty does not prevent public authorities to step in and adopt protective measures[362]. Choosing either of these regulatory principles generally means prioritizing certain values to the detriment of others: on the one hand, the cost-benefit analysis emphasises economic efficiencies and quantifiable benefits, on the other the precautionary principle "pursue safety and health concerns over economic costs"[363]. Many scholars have seen in this difference a confrontation between the civilized and cautious Europe with the risky and incautious America[364].

[358] BERGKAMP L., KOGAN L., *Trade, the Precautionary Principle and Post-Modern Regulatory Process*, in *European Journal Risk Regulation*, 2013, p. 497
[359]Executive Order No. 12,866, 58 Fed. Reg. 51,735, 30 September 1993
[360] Industrial Union Department, AFL-CIO v. American Petroleum Institute, (*The Benzene Case*), 448 U.S. 607 (1980) The Court ruled that "benzene could be regulated only if it posed a significant risk of material impairment"
[361] Ibid.
[362] Case C-180/96 *United Kingdom v. Commission*, 1998, ECR 1-2265, p.99
[363] FUNG S., *Negotiating Regulatory Coherence: The Costs and Consequences of Disparate Regulatory Principles in the Transatlantic Trade and Investment Partnership Agreement Between the United States and the European Union*, in *Cornell International Law Journal*, 2014, p. 449
[364] RICHTER S.G., *The US Consumer's Friend*, in *New York Times*, 21 September 2000

2.1.3 The *Hormones* case - Different understanding of the precautionary principle between EU and US

In order to analyse more deeply the existing gap looking from the angle of the precautionary principle, the *Hormones case*[365] is, definitely, one of the most interesting WTO disputes between the EC one the one hand and U.S. and Canada on the other. In this case, in fact, the SPS Agreement has been used to challenge European health and safety regulations concerning hormone-treated meat. In particular, the case dealt with the EC prohibition[366] on the placing on the market and the importation of meat products treated with certain hormones. On the one hand, the ban reflected the EU approach to food safety policy (i.e. the precautionary principle), on the other hand its effect was to restrict the trade of meat products coming from countries[367] where animals are regularly treated with growth-promoting hormones.

Therefore, in response to this ban, the U.S. suspended trade concessions with the EU by imposing higher import tariffs on EU products[368] and in 1996 both Parties requested WTO consultations to solve the dispute. This case related to Articles 3.1, 3.3[369], 5.1[370]

---

[365]Panel Report, EC Measures Concerning Meat and Meat Products, document WT/DS26/R/USA, 18 August 1997; WTO Appellate Body Report, European Communities - EC Measures Concerning Meat and Meat Products, Document WT/DS26/AB/R; WT/DS48/AB/R, 16 January 1998

[366]Council Directives 81/602/CEE, (July 1981); 88/146/CEE, (7 March1988); 88/299 (May 1988). These Directives have been replaced by the Directive 96/22/CEE, by which the above-mentioned prohibition was enacted and in which the six prohibited hormones were listed. This Directive has been modified by the Directive2003/74/CE and by the Directive 2008/97/CE

[367] In the United States hormones have been approved for use since the 1950s and are used on almost 90% of the cattle on feedlots. According to the US Food and Drug Administration (FDA) and the US Department of Agriculture hormones in beef have no physiological significance for humans. Growth-promoting hormones in beef are used also in Canada, Australia, Mexico, Chile and other countries.

[368] JOHNSON R., *The US-EU hormone dispute*, Congressional Research Service, 2015, CRS Report R40449, p. 18 "The first US action in 1989 imposed retaliatory tariffs of 100% ad valorem duty on selected food products and remained in effect until 1996. In 1999 the same action was undertaken

[369] Article 3.3 SPS Agreement " Members may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations…they shall not be inconsistent with any other provision of this Agreement"

[370] Article 5.1 SPS Agreement "Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations"

and 5.7[371] of the SPS Agreement and according to the Panels first and the Appellate Body (AB) then, the EU acted inconsistently with these provisions, since the EU risk assessment on the cancerogenic effect of hormones was not based on a scientifically sound risk analysis for human health.

The EU claimed that this ban was supported by studies confirming that hormone-treated meat may cause potential harmful effects to human health. The rationale of this position "*evolved initially, as a reaction to reports in the 1970s over the illegal use of DES[372] (dethystilboestrol) in veal production in France and then, in the 1990s to the outbreak of the BSE crisis*"[373]. These two events contributed further to an unfavorable political and social environment for resolving the *Hormones case*, because in citing the widespread consumer anxiety the EC "*implicitly equated consumer fears over hormone safety with actual public health needs*"[374].

Therefore, albeit legal uncertainty and the fact that two of the six growth-hormones at stake were not found to be hazardous to health, the ban was adopted anyway because, as the EC agricultural commissioner explained, "*scientific opinion on the case was essential, but not determinative"*[375]. According to the US, while the EU risk assessment was inconsistent for several reasons[376], its position was supported by "*scientific reviews*

[371]Article 5.7 SPS Agreement "In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members"

[372] DES was thought to be the reason of hormonal irregularities discovered on many adolescents

[373] JOHNSON R., *The US-EU hormone dispute*, Congressional Research Service, 2015, CRS Report R40449, p. 3

[374] CARTER M., *Selling Science under the SPS Agreement: Accommodating Consumer Preference in the Growth Hormones Controversy* in *Minnesota Journal of Global Trade*, Vol. 6, Issue 2, 1997, p. 627

[375] VOGEL D., *Barriers or Benefits: Regulation in Transatlantic Trade*, Washington DC: Brooklings Institute Press, 1997, p.15

[376] Research carried out until now has not provided proof of damage to human health caused by this product; many unscientific assumptions were added by the EC; other foodstuffs contain similar hormones and often in larger quantities; the EC continues to allow human consumption of domestically produced meat from animals administered with the banned hormones for therapeutic purposes

of the six hormones, international standards and a long-standing history of administering the six hormones to cattle for growth promotion purposes"[377].

The EC contested the way how US, Canada and the Appellate Body handled the risk, because under the SPS Agreement risk is "a qualitative and not a quantitative concept"[378], it means probability of adverse effect too.

This issue about legal uncertainty has led to the discussion about the status of the precautionary principle and its application under the SPS Agreement. By citing its longstanding policy of precaution and recalling contemporary examples[379] of health hazards once thought safe, the EC rejected the American assertion that the scientific data on hormones were conclusive. On the other hand, both Canada and US expressed the idea that precaution can only be handled as a flexible approach and not as a general principle of law thereby its application cannot replace risk assessment and adequate scientific proofs[380] as required by Article 5.1 SPS Agreement. The Appellate Body solved this discussion claiming that it is a legal principle and not an approach since "the precautionary principle indeed finds its reflection in Article 5.7 SPS Agreement"[381].

Anyway, this case made clear that while in the EU the approach of "better safe than sorry"[382] lies at the core of the decision-making process, US and Canada give the benefit of doubt to the producer. "They will not protect consumers unless there is clear and weighty evidence of harm, in turn Europe places more emphasis on the needs of

[377] First written submission of the United States, Continued Suspension of Obligations in the EC-Hormones Dispute, WT/DS320
[378] Appellate Body Report, European Communities - EC Measures Concerning Meat and Meat Products, Document
WT/DS26/AB/R; WT/DS48/AB/R, 16 January 1998, par.27
[379] Such as the E.Coli virus and bovine spongiform encephalopathy (BSE).
[380] Appellate Body Report, European Communities - EC Measures Concerning Meat and Meat Products, Document
WT/DS26/AB/R; WT/DS48/AB/R, 16 January 1998, par. 43
[381] See note 378, par. 124
[382] VEINLA H., *Free Trade and the Precautionary Principle* in *Juridica International*, Vol. 8, 2003 p. 192

the consumer whenever safety is an issue"[383]. As Wirth[384] underlines, in fact, "there is no way to infer regulatory outcomes solely on the basis of scientific data, because most regulations are implicitly or explicitly designed to respond to social, economic, or political contexts". Therefore, in his view, science plays a role in determining health goals as far as such goals have been determined by a certain society.

In this regard, the different American and European social background has been emphasized also by the European Commissioner[385] for the Environment in 2002, highlighting that: "Europeans are more sceptical than Americans about the possibility for technological advance through the market solving our natural problems", "in the US. people are concerned about their local environment, while in Europe there is a greater understanding of the international and global dimension of the environmental challenge.".

Yet, in addition to these reasons, the role played by the US economic interests cannot be denied. In fact, the reluctance towards the precautionary principle has been mainly evident in those economic sectors where American interests are more vulnerable[386], such as the energy sector, the use of GMOs in food products and of hormones in animals. On the other hand, Europeans are very sensitive about their food and, as the Hormones dispute shows, if the WTO SPS Agreement has not been able to harmonize such positions, one should ask how and why the TTIP may achieve this goal.[387] In fact, even if in 2009 the US and the EU signed a Memorandum of Understanding (MOU)[388]

---

[383] CARTER M., *Selling Science under the SPS Agreement: Accommodating Consumer Preference in the Growth Hormones Controversy* in *Minnesota Journal of Global Trade*, Vol. 6, Issue 2, 1997, p 642

[384] WIRTH A. D., *Symposium: The Role of Science in the Uruguay Round and NAFTA Trade Disciplines*, in Cornell International Law Journal, Volume 27, Issue 3, 1994, p. 833

[385] Speech 02/184 to the European Institute of Margot Wallstrom, *EU and US Approaches to Environmental Policy*, Washington DC, 25 April 2002

[386] See note 382, p. 193

[387] BONORA G., *Sul difficile nodo della carne trattata con ormoni nel "Transatlantic trade and investment partnership (TTIP)*, in *Rivista di diritto agrario*, 2016, fasc. 1, pt. 1, p. 130

[388] WTO, European Communities—Measures Concerning Meat and Meat Products (Hormones), Joint Communication from the European Communities and the United States, WT/DS26/28, 30 September 2009. Currently the EU has granted market access to US exports of "high quality beef" (beef raised without growth hormones) and the US has suspended higher duties for imported EU products listed under the dispute

to solve this long-standing dispute, there are many other food security issues where it will be very hard to find a compromise during the TTIP negotiations. This is even more true considering that the US proposal on "science and risk" in the SPS Chapter while not eliminating the precautionary principle, contains no reference to it at all. This is the reason why, in the EU public debate, "*the precautionary principle appears to be a kind of counterweight to industrialization, globalization and Americanization…*"[389].

2.1.4 The wide gap between EU and US on the Genetically Modified Organisms and chlorine-treated poultry regulations

As highlighted in the previous paragraph, regulatory approaches sometimes differ on either side of the Atlantic because of cultural difference and public attitude. Along with the hormone-treated meat, other examples in this regard, concerns Genetically modified (GM) foods[390], pesticides and chlorine-washed chicken. Since they represent the most sensitive food issues where the EU and the US provides for divergent levels of protection, it has been said that they may amount to "potential deal breaker[s] for TTIP"[391].

Regarding GMOs, the EU Commission made clear that "the EU has very detailed legislation that lays out when and how genetically modified products can be grown or sold in the EU. Our rules do allow some products to be imported and grown but they are much stricter than comparable US rules. In a case like this, it is not possible to make the systems compatible, because we have taken different democratic decisions through our legislative processes about what rules are right for our societies. TTIP will do

[389]WIENER J. B., ROGERS M. D., *Comparing Precaution in the United States and Europe*, in *Journal of Risk Research,* 2002, p.2

[390] This expression refers to plants or animals bred to have higher yield or to resist disease, by modifying their cellular and genetic make-up.

[391] ALONS G., *The TAFTA/TTIP and Agriculture: Making or Breaking the Tackling of Global Food and Environmental Challenges?*, in *THE TRANSATLANTIC COLOSSUS: Global contributions to broaden the debate on the EU-US Free Trade Agreement*, 2014, p. 65

nothing to change those laws".[392] The main regulatory difference is that while the EU, relies on the precautionary principle, meaning that before approving these new products, relevant evidences about their safety is required, the US considers GM foods as "substantially equivalent to unmodified products"[393], permitting activities to proceed until any showing of significant harm.

This divergence, likewise for the growth-hormones case, has already been at the core of the so-called EC-Biotech dispute[394] before the WTO Dispute Settlement Body in 2003. Between 1999 and 2003 the EC has provided for a complex pre-market approval system for the placing on the market and release into the environment of GMOs[395]. Yet, it was so difficult to comply with such procedure that the result was that none of the products concerned was approved, albeit not being formally rejected[396]. Therefore, on May 2003, US Canada and Argentina filed complaints with the WTO claiming that the EU measure amounted to unfair protectionist behaviour against GMOs coming from their countries.

The Panel ruled in favour of the US, claiming that the EU's measure entailed a "general *de facto* moratorium on approvals of biotech products"[397], inconsistent with the WTO SPS Agreement, because the health risk created by GMOs was not sufficiently scientifically based.[398] Nor this case, neither the new EU regulatory framework on

[392]European Commission, *TTIP and regulation: an overview,* 10 February 2015, p.7

[393] LESTER S., BARBEE I., *The challenge of cooperation: Regulatory Trade Barriers in the Transatlantic Trade and Investment Partnership*, in *Journal of International Economic Law*, 2013, 16, p. 855

[394] EC-Measures affecting the approval and marketing of biotech products, WT/DS291/R (2006). For an overview on the case see BEVILACQUA D., *La sicurezza alimentare negli ordinamenti giuridici ultrastatali*, Milano, 2012, p.201

[395] Directive 90/220/EC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms. Later modified by Directive 2001/18/EC. This Directive has been amended by Decision 2002/623, Regulation 1829/2003 and Regulation 1830/2003

[396] ALABRESE M., *TTIP e agroalimentare. Prime riflessioni a margine delle proposte dell'Unione Europea nella negoziazione della "Trans-Atlantic trade and investment partnership* in *Rivista di diritto agrario,* 2016, fasc. 2, pt. 1, p. 224

[397] It was general in that it applied to all applications for approval pending in August 2003 under the relevant EC legislation, and de facto because it had not been formally adopted. Approvals were prevented through actions or omissions by a group of five EC member States and/or the European Commission

[398] PETERSON M. J., *The EU-US Dispute over Regulation of Genetically Modified Organisms, Plants, Feeds, and Foods*, 2010, p.8

GMOs[399] have been able to reconcile these different understandings of the interplaying of food and biotechnologies. EU law, in fact, uses to consider also the "*social, ethical and economic aspects*" of food regulation and such practice necessarily affects its evaluation of food technologies[400]. On the other hand, legitimate factors like consumers attitude and animal welfare are not explicitly acknowledged within the US legislation in the same way. In this regard, it has also been demonstrated that while European consumers[401] are very reticent in accepting GM technology, in the US there is a stronger consumer acceptance of genetically modified foods.

These divergent attitudes are clearly reflected in the even more divergent EU and US legal frameworks. The U.S. approach focuses on the product: GM and conventional foods are subject to the same regulations because despite the different processes used to make them, the final products are considered to be similar[402]. The GMOs policy is set forth in the "Coordinated Framework for Regulation of Biotechnology" (CFRB)[403], which adopted in 1986 and updated through the years, is still considered valid. This document, claiming that regulation should focus on the nature of the final food product rather than the process by which that food is made, provides only general guidelines, without setting an *ad hoc* regime for GMOs[404].

Therefore, by adopting the doctrine of substantial equivalence to conventional foods, the US has prevented agencies from regulating technologically modified foods

---

[399] On April 2004, the GM Package came into force. The core of EU regulatory framework on GMOs are Regulation 1829/2003 on GM food and feed, Regulation 1830/2003 on traceability and labelling of GMOs.

[400] KNOLL K., *Safeguarding Consumer Rights and Protection in TTIP*, in CARDOSO D. (ed.) *The Transatlantic colossus: global contributions broaden the debate on the EU-US free trade agreement*, 2013, p. 30

[401] A 2010 survey showed that 57% of Europeans are opposed to GM foods because there is a widespread feeling that GMOs are unnatural. For a more detail view see GASKELL G. Europeans and Biotechnology in 2010: Winds of Change?, Report to the European Commission's DG for research, October 2010, p. 37-38

[402] LAU J., *Same Science, Different Policies: Regulating Genetically Modified Foods in the U.S. and Europe*, in *Genetically Modified Organisms and Our Foo*d, August 2015, available at http://sitn.hms.harvard.edu/what-is-sitn/

[403] Adopted during the Reagan administration, by the White House Office of Science and Technology Policy

[404]VISANI S., *Modelli normativi a confronto: Regolamentazione degli OGM tra UE e USA*, in *Rivista di diritto alimentare*, Anno IX, numero 3, p. 63

differently than unmodified products, with equivalent physical features and characteristics[405]. Therefore, in the absence of scientific proof that any harm is caused by their sale or consumption, US legislators give GMOs no additional oversight[406].

Moreover, according to the Food and Drug Administration (FDA), GM foods are "generally recognized as safe" (GRAS) and this assumption has two main consequences. First, as far as GMOs are substantially equivalent to conventional food in terms of overall composition, they do not have to be approved before entering the market. It means that a pre-market approval is the exception[407], while under EU law this it is the rule. Second, GM foods are only labelled on a voluntary basis[408], therefore producers are not obliged to provide for a different labelling system. Yet, while the FDA has no mandatory labelling requirements for GM foods, statistics have shown that almost ninety percent of American consumers are in favour of labelling GMOs[409].

Considering all these aspects, it is easy to understand why US producers have long complained about the EU approach and are still complaining during the TTIP negotiations. In fact, the EU refusal of the doctrine of the substantial equivalence and content-based labelling make EU regulations on GM foods stricter than the American ones[410].

Definitely, the consumers' trauma related to the food safety crises of the 1990s, along with the EU's risk-averse culture have been among the leading factors for the

---

[405] WATTS J., *The Transatlantic Trade and Investment Partnership: An Overly Ambitious Attempt to Harmonize Divergent Philosophies on Acceptable Risks in Food Production without Directly Addressing Areas of Disagreement* in *North Carolina Journal of International Law*, Vol. 41, Issue 1, 2015, p. 104

[406] KYSAR D. A., *Preferences for process/product distinction and the regulation of consumer choice*, in *Harvard Law Review*, 2004, p. 557

[407] The FDA calls upon companies to go through a voluntary consultation process to determine whether their new GM food would require premarket approval. Pre-market approval (which happens rarely) is necessary only as far as GM foods contain high levels of toxic substances or allergens or reduced levels of important nutrients.

[408] Coordinated Framework for Regulation of Biotechnology, 51 Fed Reg, 26 June 1986

[409] HENSLEY S., *Americans are wary of genetically engineered foods*, in *NPR*, November 2010, p.1 available at https://www.npr.org/

[410] MANSOUR M., KEY S., *From farm to fork: the impact on global commerce of the new European Union Biotechnology Regulatory scheme*, in *The International Lawyer*, Vol. 38, No. 1, 2004, p. 66

development of the current EU GM food regulation. The first difference with the US is that genetically modified foods are subject to a separate regulatory framework under EU law, which now is the "GM package"[411]. Moreover, the EU relies on the precautionary principle meaning that since potential risks of GM foods are not completely known, "*regulatory decisions err on the side of caution and require a high burden of proof for product safety*"[412].

In this regard, it must be underlined that Article 4.2 of Regulation 1829/2003 sets forth a general prohibition on GMOs for food use, stating that "*no person shall place on the market a GMO for food use or food referred to in Article 3(1) unless it is covered by an authorisation granted in accordance with this Section and the relevant conditions of the authorisation are satisfied*"[413].

Therefore, in the EU all GM food products must go through a centralized process for premarket approval, governed by the so-called "one door one key" principle. According to this principle, as far as the authorisation for GM foods is provided, it is valid throughout the European Union. Furthermore, it means that "the single application is based on a single risk assessment process, under the EFSA responsibility and a single risk management process, involving both the Commission and the Member States through a regulatory committee procedure"[414].

For what concerns the label, EU law impose clear labelling[415] of GMOs placed on the market in order to enable consumers as well as professionals (e.g. farmers, and food feed chain operators) to make an informed choice. Obviously, having to produce and label products differently for different markets represents an additional cost for

[411]Regulation 1829/2003, Regulation 1830/2003, Commission Regulation 65/2004 and 641/2004, Directive 90/219/EEC, Commission Recommendation C (2003) 2624
[412] See note 406, p. 560
[413]Food referred to in Article 3(1) must not: (a) have adverse effects on human health, animal health or the environment; (b) mislead the consumer; (c) differ from the food which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for the consumer
[414] SINOPOLI D., KLUIFHOOFT J., VAN DER MEULEN B., *Authorisation requirements,* in VAN DER MEULEN B., VAN DER MEULEN M. (eds.) *EU food law Handbook*, Wageningen, 2014, p. 280
[415] No indication needed for products containing traces of GMOs below 0.9 %, if this is technically unavoidable

producers and this is why American producers comply that EU laws hinder their exports[416]. Therefore, despite both American and European rhetoric supporting regulatory coherence in the TTIP, both entities seem to remain unwilling to compromise on these specific regulatory standards.

This assumption is even more true for what concerns another hot issue in the food sector, the chlorine-treated poultry[417]. In particular, the current debate concerns whether or not TTIP endangers the 1997 EU ban on chlorine-washed chicken, prohibiting the import of poultry treated with any substance other than water unless that substance has been approved under EU law. Despite the EFSA findings[418] that this process is safe, the European Commission has been prevented from lifting the ban by resistance from veterinary experts and Members of European Parliament (MEPs).[419] Once again, the US government has challenged the ban through the WTO[420] and in 2009 a panel was established.

Yet, since the EU cannot prove that such treatment is hazardous for human health, it is not unlikely that its ban may be found in breach of WTO rules. However, "even if the case advances to a dispute resolution panel, a solution appears to be elusive. The two sides maintain widely divergent views not only on the poultry issue but on some aspects of their basic approach to food safety regulation"[421]. Chlorinated chicken has become symbolic of the potential negative effects on EU consumers that TTIP may cause and

---

[416] LESTER S., BARBEE I., *The challenge of cooperation: Regulatory Trade Barriers in the Transatlantic Trade and Investment Partnership*, in *Journal of International Economic Law*, 2013, 16, p. 885

[417] Chlorine is used as a Pathogen Reduction Treatment (PRT) that US producers use to wash bird carcasses when preparing them for sale.

[418] EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), 2014. *Scientific Opinion on the evaluation of the safety and efficacy of peroxyacetic acid solutions for reduction of pathogens on poultry carcasses and meat*, in *EFSA Journal*, 2014

[419] HILARY J., *The Transatlantic Trade and Investment Partnership: A charter for deregulation, an attack on jobs, an end to democracy*, 2014, p. 20, available at https://rosalux.gr/sites/default/files/publications/ttip_web.pdf

[420] European Communities – Certain Measures Affecting Poultry and Poultry Meat Products from the United States, 24 February 2010, WT/DS389/4

[421] JOHNSON R., *U.S.-EU Poultry Dispute, Congressional Research Service Report R40199, 2010 p.2*

the ban on imports of "chicken in chlorine sauce" has been supported by EU leaders too.[422]

Considering this philosophical divide on either side of the Atlantic, the Commissioner Karel De Gucht made clear "where the gap in approach between the EU and the US is too wide, we just won't change our rules: we will not import any meat that is treated with hormones; we will not give a blanket approval of imports of GMOs"[423].

Yet, despite these reassurances, it must be noted that in the EU proposal for legal text on "Regulatory Cooperation" in TTIP[424] there is no reference to the exclusion from negotiations of the hormone-treated meat, GMOs and chlorine-treated poultry. Moreover, since in the EU all these matters are governed by the precautionary principle, the will of the United States Trade Representative (USTR) "to eliminate or reduce non-tariff barriers that distort trade and restrictions that are not based on science"[425], makes clear that the application of this principle to food safety regulations represents one of the greatest challenges in reaching the TTIP Agreement.[426]

[422] WINTER C., *Europe Dreads America's Chlorinated Chickens*, in *BLOOMBERG BUSINESSWEEK*, 8 August 2014 The German Chancellor Angela Merkel assured that TTIP would not lead to the importation of chlorinated chicken, claiming that "I have prevented those imports for years, and I will continue to prevent them. No question"

[423]Statement by Commissioner Karel De Gucht on TTIP, Strasburg, 15 July 2014 avaiable at http://europa.eu/rapid/press-release_SPEECH-14-549_en.htm

[424]Made public on 21 March 2016, http://trade.ec.europa.eu/doclib/docs/2016/march/tradoc_154377.pdf

[425]OFFICE OF THE UNITED STATES REPRESENTATIVE, *U.S. Objectives, U.S. Benefits In the Transatlantic Trade and Investment Partnership: A Detailed View*, 2014, available at *https://ustr.gov/*

[426] See note 419, p. 18

2.1.5 From the Investor-State dispute settlement (ISDS) towards the Investment Court System (ICS)

As underlined in the previous paragraphs, food security issues represent one of the biggest challenges in the contest of regulatory convergence. In fact, if the gap between EU and US is too wide, EU food safety standards, which are much stricter than the American ones, may be reduced to ensure regulatory equivalence. This possibility can be clearly understood only as far as the role played by transnational corporations in the TTIP negotiations is acknowledged as well. Critics, in fact, suggest that the involvement of enterprises in the negotiations is a "signal that the agreement will result in lower mutual standards since the outcome would maximize profits"[427].

Yet, in sensitive areas such as consumer protection and food security, this "*race to the bottom is unlikely to be an acceptable compromise*"[428]. These fears become even more true considering the Investor-State dispute settlement (ISDS)[429], since it would grant transnational corporations the right to sue individual states directly for losses suffered under their jurisdictions as a result of public policy decisions. Hence, "*the EU may be convicted in a state-investor procedure it its food law have an expropriating effect*"[430].

Anyway, one should not forget that the ISDS clause is not a recent phenomenon[431] and it represent a crucial and positive evolution for what concerns the role of individuals

[427] VON ENDT M., *Is TAFTA/TTP a Race to the Bottom in Regulatory Standards?: The Case of Hormone Treated Beef* in *The transatlantic colossus: Global contributions to broaden the debate on the EU-US Free trade agreement*, Daniel Cardoso et al. eds., 2013, p.100 "As a matter of fact, negotiators have so far invited far more business than civil society groups to the negotiation table, which suggests that corporate interests, and thus profits, play a major role in the trade agreement"

[428]GOYENS M., *Consumers at the heart of the Transatlantic Trade and Investment Partnership (TTIP), BEUC Position statement* BEUC-X-2014-031, 6 May 2014, p. 6

[429] CALVANO R., *Chi ha paura dei TTIP leaks? Brevi spunti sulla tutela dell'ambiente e di altri "beni comuni" tra prospettiva europea, internazionale e problemi di riassetto del regionalismo* in *Osservatorio costituzionale,* fasc. 2, 2016 p.5

[430] SCHROEDER W., *Transatlantic Free Trade agreements and European Food standards*, in *European food and feed Law Review*, 2016, p. 494

[431] It can be traced back to the first Bilateral Investment Treaty (BIT) concluded in 1959 between Germany and Pakistan and to the 1965 Washington Convention, setting the International Centre for Settlement of International Disputes (ICSID) see DEL VECCHIO A., *I tribunali internazionali, tra globalizzazione e localismi,* Bari, II ed., p. 76-85

under international law.[432] The rationale of this system, in fact, lies in the need to provide first, an alternative solution to the diplomatic protection offered by the State of nationality of the investor and secondly to avoid the resort to domestic courts.[433] In both cases the aim is to prevent a legal dispute to become a political issue between States[434].

More than 3000 international investment treaties allow foreign investors to sue the governments of countries in which they invest for violating their property rights[435]. The EU itself, as well its Member States are party to around 1 400 agreements which provide for ISDS[436].

Yet, since the entry into force of the Lisbon Treaty in 2009, Article 207.1 TFEU[437] by including foreign direct investments under the common commercial policy, gives the EU an exclusive competence on this sector[438]. However, "exclusive" doesn't mean that Member States are excluded *tout court* when it comes to investment treaties, but only that negotiating such agreement will be up to the Commission, while for the ratification process, having regard to the matters concerned, also Member States may be involved[439]. As will be discussed later[440], doubts concerning the extension and limits

[432] In this sense see, inter alia, FOCARELLI C., International Law as a Social Construct, Oxford, 2012, p. 184-189

[433] MAURO M. R. *Investimenti Stranieri*, in *Enciclopedia del diritto*, Annali, IV, Milano, 2011, p. 650-658

[434] See, inter alia, GALLO D., NICOLA F., *The External dimension of EU investment Law: Jurisdictional Clashes and Transformative Adjudication*, in *Fordham International Law Journal*, 2016, p. 1090-1096

[435]European Parliamentary Research Service, *Investor-State Dispute Settlement (ISDS) State of play and prospects for reform*, 21 January 2014, available at http://www.europarl.europa.eu/

[436] European Commissioner for trade Karel De Gucht, *Statement by Commissioner Karel De Gucht on TTIP*, 15 July 2014. On the international investment law issues in the EU framework see, MAURO M. R., *Accordi internazionali sugli investimenti e Unione europea*, in *Studi sull'integrazione Europea*, Year V, 2010, p. 403-430

[437] "The common commercial policy shall be based on uniform principles, particularly with regard to..foreign direct investment...The common commercial policy shall be conducted in the context of the principles and objectives of the Union's external action"

[438] Article 3, par.1, lett e) TFEU "The Union shall have exclusive competence in…common commercial policy"

[439] GALLO D., *Scope, extent and limits of the new system of the investment disputes resolution in the recent free trade agreements of the European Union* in *Il Diritto del commercio internazionale*, 2016, fasc. 4, p. 828

[440] See Chapter 2, par.2.3.3

of the EU exclusive competence on investments, have been clarified in 2017 by the ECJ advisory opinion 2/15 concerning the free trade agreement with Singapore (EUSFTA)[441].

Anyway, it was with the completion of CETA negotiations with Canada and the opening of TTIP negotiations, conducted by the Commission on behalf of the Member States, in accordance with Article 207 TFEU, that the issue of ISDS has come to public attention in the EU[442]. The critical statement of The Economist, is clear in this regard: "If you wanted to convince the public that international trade agreements are a way to let multinational companies get rich at the expense of ordinary people, this is what you would do: give foreign firms a special right to apply to a secretive tribunal of highly paid corporate lawyers for compensation whenever a government passes a law to, say, discourage smoking, protect the environment or prevent a nuclear catastrophe.

Yet, that is precisely what thousands of trade and investment treaties over the past half century have done, through a process known as 'investor-state dispute settlement,' or ISDS."[443] This mechanism has historically been included in Bilateral investment Treaties (BITs)[444], between countries with very different legal and judicial standards, in order to allow investors of one Party to resort to an international arbitration in case of possible arbitrary acts carried out by the host country (such as unlawful expropriations)[445].

---

[441] Opinion 2/15 of the European Court of Justice, 16 May 2017, available at http://curia.europa.eu

[442] See note 439, see also *ALGOSTINO A., ISDS ("investor-state dispute settlement"), the heart of darkness of the "global economic governance" and the constitutionalism* in *Costituzionalismo.it*, 2016, fasc. 1, p. 103-174, CALAMITA M.R., *La «clausola ISDS» negli accordi commerciali di ultima generazione dell'Unione europea*, in *"Diritto pubblico comparato ed europeo, Rivista trimestrale*" 2/2017, p. 307-340

[443] Investor-State Dispute Settlement: The Arbitration Game, in *THE ECONOMIST*, 1 October 2014, avaiable at http://www.economist.com/news/finance-and-economics/21623756-govern

[444] For a general overview on Bilateral Investment Treaties see MAURO M. R., *Gli accordi bilaterali sulla promozione e protezione degli investimenti*, Torino, 2003

[445]ISDS was created to reduce the political risks related to rapidly increasing foreign investment, and make the commitments made by host states in investment treaties more easily enforceable see SCISO E., *Gli investimenti privati stranieri*, in *Appunti di diritto internazionale dell'economia*, Giappichelli, III ed., 2017, p. 191-210

Yet, due to the fact that both US and EU have well-functioning court systems and robust private property rights, TTIP opponents argue that this agreement "*does not warrant the added protection of an ISDS chapter since both parties' legal systems sufficiently protect foreign investors*"[446].

Moreover, the alleged lack of either transparency of ISDS procedures and of arbitrators' impartiality, the absence of the possibility of appeal, along with the fear that this mechanism would grant unprecedent powers to US corporations over any new public health or food safety regulations, were among the main criticism raised by the EU public opinion. In fact, in 2014 the Commission opened a public consultation on ISDS[447] and the result was ninety-seven percent of citizens disfavouring this system[448].

Therefore, in 2015, the Concept paper on "Investment in TTIP and beyond – the path for reform. Enhancing the right to regulate and moving from current ad hoc arbitration towards an Investment Court"[449] first, and the EU Commission "TTIP textual proposal on investment protection and Court System"[450] then, developed a reformed approach on investment protection. The main innovative elements of the proposal are the strengthening of the States' right to regulate and to achieve legitimate policy objectives[451], the establishment of a new system for resolving disputes (The Investment

[446]KRAJEWSKI M., *Why TTIP Has To Be Rethought*, in *Social Europe*, 2014, p. 1, avaiable at https://www.socialeurope.eu/isds-ttip-rethought

[447]Online public consultation on investment protection and investor-to-state dispute settlement (ISDS) in the Transatlantic Trade and Investment Partnership Agreement (TTIP), 27 March-13 July 2014

[448] European Commission, Commission Staff Working Document, Report SWD (2015), Brussels, 13.1.2015 The report on the results of the consultation, identified four areas where particular concerns were raised: i) the protection of the right to regulate; ii) the establishment and functioning of arbitral tribunals; iii) the review of ISDS decisions through an appellate mechanism; iv) the relationship between domestic judicial systems and ISDS.

[449] 5 May 2015, avaiable at http://trade.ec.europa.eu

[450] 12 November 2015, avaiable at http://trade.ec.europa.eu

[451] Section 2, Article 2 "The provisions of this section shall not affect the right of the Parties to regulate within their territories through measures necessary to achieve legitimate policy objectives, such as the protection of public health, safety, environment or public morals, social or consumer protection or promotion and protection of cultural diversity"

Court System)[452] and the creation of an Appeal Tribunal[453] to hear appeals from the awards issued by the Tribunal.

As the Commission itself makes evident[454], this new approach relies on several innovations[455] concerning investment protection rules and the ISDS mechanism, which represented a model for the negotiations with Canada (CETA) and Vietnam (EUVFTA). In short, this shift from an arbitral towards a quasi-jurisdictional system[456] amounts to the Commission' acknowledgement that the previous system was significantly flawed.

Yet, "*in order for this evolution to become a true and effective revolution, the EU should ensure that the principle of autonomy of the EU legal order, including the interpretative monopoly of the CJEU, shall be respected"*[457]. However, the US has not replayed to this proposal yet, at least publicly. Albeit the EU proposal contains explicit and detailed rules concerning when and how investors can sue States[458], the doubts related to the risk that the host State may be forced to pay compensation for having

[452] EU Commission Proposal, Chapter 2, Sub-section 4, Article 9-12
[453] Ibid, Article 10
[454] European Commission Concept paper on "*Investment in TTIP and beyond – the path for reform Enhancing the right to regulate and moving from current ad hoc arbitration towards an Investment Court"* p.1, see also *Factsheet on Investment Protection and Investor-State Dispute Settlement,* 7 January 2015. In addition to the factsheet the European Commission published two summaries of its position on ISDS: 2013 ISDS Summary and 2014 ISDS summary.
[455] The following are among the most relevant ones: reaffirmation of States' right to regulate and to achieve legitimate policy objectives (such as public health, safety, environment), the provision of rules ensuring the early dismissal of unfounded claims and the "loser pays principle", defining key concepts like "fair and equitable treatment" and "indirect expropriation" in order to prevent abuse, introduced full, mandatory transparency of the arbitration process, including, for the first time, a code of conduct for arbitrators, ensuring the respect of high ethical and professional standards
[456] The evidence of the quasi-jurisdictional nature of this system appears clearly by the fact that the arbitrators are replaced by judges, who shall be appointed for a six-year term. (Article 10, par.5) Moreover, it's the first time that an Appeal Tribunal is included into a trade and investment agreement. For a general overview on the evolution of the concepts of international arbitration and jurisdiction see DEL VECCHIO A., *I tribunali internazionali, tra globalizzazione e localismi*, Bari, II ed., p. 293-299
[457] GALLO D., *Scope, extent and limits of the new system of the investment disputes resolution in the recent free trade agreements of the European Union* in *Il Diritto del commercio internazionale*, 2016, fasc. 4, p. 828
[458] Sub-section 5: Conduct of proceedings, Articles 13-17

introduced protective laws of consumers, food safety and environment, are still alive[459]. Two often cited cases in this regard, are the lawsuit by Philip Morris against Australia for introducing the 2011 Tobacco Plain Packaging Act, for limiting the use of cigarettes[460] and the case of the Swedish firm against Germany for the German nuclear Phase-out[461].

[459] ALABRESE M., *TTIP e agroalimentare. Prime riflessioni a margine delle proposte dell'Unione Europea nella negoziazione della "Trans-Atlantic trade and investment partnership* in *Rivista di diritto agrario*, 2016, fasc. 2, pt. 1, p. 212

[460] All documents are avaiable on the Australian Government website at https://www.australia.gov.au

[461] Vattenfall AB and others v. Federal Republic of Germany, ICSID Case No. ARB/12/12, avaiable at www.icsid.worldbank.org

2.1 Comprehensive Economic and Trade Agreement (CETA): the agreement between EU and Canada

2.2.1 The political decision on the "mixed" nature of CETA: the twin Agreement of TTIP

While the free trade negotiations between the European Union and the United States has failed, even if "nobody is really admitting it"[462], the Comprehensive Economic and Trade Agreement (CETA) with Canada is one of the most ambitious and progressive trade agreements the EU has ever concluded[463]. Canadian and European Leaders announced, during the 2009 Canada-EU summit, the launch of CETA negotiations[464].

This agreement was signed on 30 October 2016[465], following the EU Member States' approval expressed in the Council. On 15 February the European Parliament gave its consent. On 16 May 2017 the Canadian side ratified CETA. Following ratification at EU level by the European Parliament and the Council, on 21 September 2017 CETA has entered into force provisionally[466]. The agreement will take full effect once all EU Member States have formally ratified it, according to their respective constitutional requirements. In this regard, a risk of non-ratification by individual member States

[462]SIMS A., STONE J., *TTIP has failed – but no one is admitting it, says German Vice-Chancellor Sigmar Gabriel*, in INDIPENDENT, 28 August 2016, available at https://www.independent.co.uk/

[463] European Commission, *Guide to the Comprehensive Economic and Trade Agreement (CETA*), July 2017, available at http://trade.ec.europa.eu

[464] CETA was based on the: *Canada-EU joint study on assessing the costs and benefits of a closer EU-Canada Economic Partnership*, 27 October 2008 and *Canada-European Union Joint Report: Toward a Comprehensive Economic Agreement*, 5 March 2009

[465] EU and Canada were confronted with a situation in which one of the Belgian regions, Wallonia, threatened to block not the signing of CETA. In particular, the Parliament of the Belgian Walloon adopted a resolution requesting the regional government not to grant full powers to the Belgian Government to sign the CETA (i.e. to refuse the signature of CETA). See Walloon Parliament, *Resolution on the Comprehensive Economic and Trade Agreement*, 27 April 2016. Eventually, CETA was signed after three days of delay.

[466] Areas that are not yet in force are investment protection and the investment court system (ICS), portfolio investment market access, provisions on camcording and two provisions related to the transparency of administrative proceedings, review and appeal at Member State level.

cannot be excluded too[467] and each country's approval procedures may take several years.[468]

However, before all Member States[469] will ratify CETA, the agreement first has to pass a significant legal test in the form of a request to the CJEU for an opinion on the agreement's compatibility with EU law.[470]

The forthcoming opinion could have far-reaching consequences the CETA ratification process. On the one hand, "a negative opinion could put CETA's future in jeopardy (at least in its current form), on the other, a positive one would strengthen CETA's legitimacy and see the legal controversy surrounding the ICS die down"[471]. However, the current CETA provisional application represents a necessary compromise in response to the political debate about the "mixed" or "EU only" nature of this agreement[472].

The legal reason to opt for a mixed agreement, is that the agreement partly falls within the competences of the Union and partly within the competences of the Member States[473]. In fact, even if Article 207 TFEU gives the EU exclusive competence regarding trade agreement, "recently concluded comprehensive trade and investment agreements often go beyond pure trade issues and extend into the realm of Member

---

[467] DOLLE T, BRUNO G., *Mixed Feelings about Mixed Agreements and CETA's Provisional Application*, in *European Journal of Risk Regulation (EJRR)*, Vol. 7, Issue 3 (2016), p. 620. For A general overview on the legal consequence of non-ratification of mixed agreement, see VAN DER LOO G, WESSEL R. A., *The non-ratification of mixed agreements: legal consequences and solutions*, in *Common Market Law Review*, 2017 p. 1-28

[468] In this regard, on 17 January 2018, the EU Commissioner Pierre Moscovici declared that CETA, will continue to provisionally apply, even if one Member State will not ratify it.

[469] Latvia, Denmark, Malta, Spain, Croatia and – most recently – the Czech Republic and Portugal have ratified the agreement

[470] This request was submitted by Belgium on 6 September 2017, as was expected as part of its internal compromise last year with the Walloon region in return for the latter's support for signing CETA. It concerns the compatibility of CETA Chapter 8 ("Investments"), Section F ("Resolution of investment disputes between investors and states") with the European Treaties. See file:///G:/CAPITOLO%202/belgio%20advisory%20opinion.pdf

[471] HARTE R., *CETA ratification process: Latest developments*, in European Parliamentary Research Service, October 2017, p.2

[472] For a more detailed classification of mixed agreements, centred on the scope and nature of the EU's competences, see KLAMERT M., *The Principle of Loyalty in EU Law*, Oxford, 2013, p. 183-186

[473] For instance, CETA Chapters: 8 on Investments and 13 on Financial Services fall under MSs competences too (portfolio investment, dispute settlement, property and expropriation aspects).

States competences"[474]. At the same time, "*the choice for mixity is not always a purely legal issue*"[475] and the case of CETA makes this evident. In fact, on June 2016 the EU Commission President Juncker declared that while, for "legal reasons" CETA should be qualified as a "EU only" one[476], "*the wish of most EU leaders is that it should be considered as a mixed agreement, implying national ratification*"[477].

In this regard, the main argument put forward by Member States, such as Germany[478] and France[479], is that ratification by national parliaments will allow citizens to give a final say over the respective agreement.[480] Therefore, in order to avoid any further debate between the EU and its Member States and to allow for a speedy signature, on July 2016 the Commission reversed course, claiming that even if *"*from a strict legal standpoint, this agreement falls under exclusive EU competence, the political situation in the Council is clear, and we understand the need for proposing it as a 'mixed' agreement"[481].

The rationale of this compromise lies in the economic opportunity behind CETA, a "*milestone in European trade policy*"[482]. In fact, EU is Canada's second most important

[474] See note 467, p. 617. Article 207.1 applies only to Foreign Direct Investments (FDI) and not to other forms of investments, such as portfolio investments (passive investments which do not involve any active management or control of the issuing company)
[475] VAN DER LOO G, WESSEL R. A., *The non-ratification of mixed agreements: legal consequences and solutions*, in *Common Market Law Review*, 2017, p. 3
[476]European Commission, *European Council endorses Commission's priorities*, Brussels, 29 June 2016
[477] European Commission, President Juncker partecipates in the European Council (28 June) and in the Informal Meeting of the Heads of State or Government of the EU-27 (29 June), 29 June 2016, available at http://europa.eu/rapid/press-release_MEX-16-2357_en.htm
[478] A challenge against CETA is currently still pending before the German Federal Constitutional Court, which is expected to rule on the matter shortly
[479] Decision No. 2017-749 DC of July 31, 2017 - Comprehensive Economic and Trade Agreement between Canada, of the one part, and the European Union and its Member States, of the other part. The French Constitutional Council ruled that CETA complies with the French Constitution
[480] See for example, BARBIERE C., *Member States claw back control over CETA*, in *EurActiv*, 6 July 2016. It has been argued that even if "political implications and public acceptance are of great importance, such decisions and determinations should not be based on political opportunism but on fact and a solid legal basis" DOLLE T, BRUNO G., *Mixed Feelings about Mixed Agreements and CETA's Provisional Application*, in *European Journal of Risk Regulation (EJRR*), Vol. 7, Issue 3 (2016), p. 620
[481] Statement by EU Trade Commissioner Cecilia Malmström, European Commission, *European Commission proposes signature and conclusion of EU-Canada trade deal*, 5 July 2016, available at http://europa.eu/rapid/press-release_IP-16-2371_en.htm
[482] See note 463, p.2

trading partner after the United States, accounting for 9.6 % of its trade in goods (exports plus imports) with the world in 2016.[483] CETA contains a wide range of provisions enabling closer economic relations, concerning commitments on the liberalisation of tariffs, investment or services, increased access to each other's public procurement markets, or disciplines on intellectual property rights (such as copyright), geographical indications, conformity assessment, subsidies and so on[484].

For what concerns the food sector, most customs duties on farm produce, processed foods and drinks will disappear. The EU will be able to export nearly 92 % of its agricultural and food products (mainly wines and spirits, fruit and vegetables, chocolate, cheese, the EU's traditional specialities, known as 'geographical indications') to Canada duty-free.[485] On the side of Canadian, which is already the fifth largest agricultural exporter in the world[486], CETA represents "*a huge opportunity to expand its agri-exports to the EU*"[487].

Yet, despite these economic benefit and trade advantages, why one of the strongest European democracy movements ever seen, signed a petition against CETA and its "twin agreement", the TTIP.[488]. The reply can be traced back to the same fears that the TTIP negotiations have raised, in particular when it comes to the Investment Court System and food security issues. In fact, owing to CETA's focus on eliminating not

[483] European Commission, *Guide to the Comprehensive Economic and Trade Agreement*, July 2017, p.10

[484] European Commission's Directorate-General for Trade, *The economic impact of the Comprehensive Economic Trade Agreement*, 2017, p. 5. This analysis predicts that once the CETA agreement is fully implemented there will be important gains through tariff elimination, FDI liberalisation for goods, and services bindings, leading to an annual increase in bilateral exports and imports between EU and Canada of at least 8%, amounting to approximately €12 billion per year additional two-way trade by 2030, split roughly evenly between the two parties.

[485]Ibid p. 8, "For some EU products such as beef, pork and corn and for Canadian dairy products, the preferential access is restricted by quotas. On the opposite, poultry and eggs will not be liberalised on either side."

[486] Canada, Agriculture and Agri-Food Canada, *We Grow a Lot More Than You May Think*, 10 April 2018, avaiable at http://www.agr.gc.ca/eng/about-us/publications/we-grow-a-lot-more-than-you-may-think/?id=1251899760841

[487] XING L., *Surprise under the table: Inspirations from the Canada-EU CETA for Enhancing Global Agri-Environment by FTAs*, in *Asper Review of International Business and Trade Law*, Vol. 13, p. 212

[488]HUBNER K., *Europe, Canada and the Comprehensive trade agreement*, New York, 2011
An argument against the approval of CETA by the EU Parliament, International Slow Food, 15 February 2017, available at *https://www.newfoodmagazine.com/*

only customs tariffs but also the so-called 'non-tariff trade barriers' in order to increase cross-border trade, agricultural and food standards will be targeted. This agreement not only incorporates WTO SPS and TBT Agreements but also complements them with further provisions, the so-called "WTO-plus" rules.

Canada, as well as the US, compared to the EU, have weaker food safety standards and less strict rules on the use of genetically modified organisms (GMOs), growth hormones, and Country of origin labelling (COOL). Critics argue that "CETA regulatory cooperation (Chapter 21) fuels a race to the bottom, where again, the focus is more on cutting costs and 'red tape' than improving health and safety."[489] CETA, in fact, incorporates "a toolbox of deregulatory measures such as requiring licensing regulations to be 'as simple as possible', 'regulatory cooperation' initiatives to synchronise regulations over time toward a single transatlantic standard, special rules to promote trade in biotechnology, and new risk assessment standards that will undermine the EU's precautionary principle"[490].

Therefore, since this agreement will take full effect only after all EU Member States have formally ratified it, before making this decision, national parliaments cannot avoid reflecting about some crucial implications for the future of European food and agriculture.

[489]IATP EUROPE, GREENPEACE NETHERLANDS, *CETA: European Food and Agriculture Standards Under Threat,* 20 September 2017, p.1

[490] TREAT S., *CETA, Regulatory Cooperation and Food Safety,* IATP, Greenpeace and Canadian Centre for Policy Alternatives (CCPA), p.1; see also MATHIS L., *Multilateral aspects of enhanced regulatory cooperation: Considerations for a Canada-EU Comprehensive Agreement (CETA),* p. 73 ss.

2.2.2 The gap between EU and Canada on Genetically Modified Organisms- the case of the *AquAdvantage salmon*

As already said, CETA as well as TTIP, focuses not only on the reduction of tariffs but mainly on the so called non-tariff barriers[491] Yet, "*the issues faced by negotiating states include to what extend regulatory harmonization is needed and it is even practicable*"[492]. In fact, even if it has been emphasized that Canada is "*a strategic partner and ally with whom we have deep historical and cultural ties*"[493], this assumption cannot be entirely accepted if transposed to the food sector.

The US and Canada in fact, have almost the same understanding of risk assessment and food regulation and thus, CETA raises the same fears related to TTIP negotiations[494]. Since the criticism raised by the use of growth-hormones and chemicals to clean animal carcasses which characterized TTIP negotiations can be transposed also to the CETA debate, the main issue worth to be analysed concerns GMOs regulation[495]. The *Frankenfish case*[496] (concerning the Canadian GM Salmon) has become the symbol of the gap existing on both side of the Atlantic.

In 1995 the Canadian government approved the first genetically modified foods,[497] introducing them into the environment and food system for the first time. Canada is the fifth largest producer of genetically engineered crops in the world[498]. On both sides of

---

[491] LEBLOND P., *The Canada-EU Comprehensive economic and trade agreement: more to it than meets the eye*, in *Policy Option Politiques*, 1 July 2010 p.74

[492] CUSLI Expert Roundtable Report: *CETA, TPP, TTIP and the Canada-US Trade Relationship*, in *Canada-United States Law Journal*, volume 39, p. 204

[493] European Commissioner for trade Cecilia Malmström, *EU-Canada trade agreement enters into force*, Brussels, 20 September 2017, http://trade.ec.europa.eu/doclib/press/index.cfm?id=1723

[494] BARBIERE C., *CETA and TTIP threaten the EU's precautionary principle***,** in *EURACTIV*, 2016, available at https://www.euractiv.com

[495] For an overview on Canadian Regulations, see Health Canada, Regulating Agricultural Biotechnology in Canada: An overview, available at http://www.inspection.gc.ca . One should not forget that a WTO dispute concerning the importation of GMOs product is still open, see WIRTH D. A., *The World Trade Organization dispute concerning Genetically Modified Organisms: Precaution meets International Trade Law*, in *Vermont Law Review*, 2013, p. 1153 e ss.

[496]MOUGEOT P. A., CETA: l'impossible traçabilité du saumon génétiquement modifié canadien, in *Le Monde Economie*, 14 September 2017, available at http://www.lemonde.fr/economie

[497] Canola varieties, GM soy, GM tomatoes (not currently on the market) and GM potatoes (not currently on the market).

[498]REHN T., TOURANGEAU W., SLATER A., HOLTSLANDER C., *Where in the world are GM crops and foods?*, Report of the Canadian Biotechnology Action Network (CBAN), 19 March 2015, p.7 In

the Atlantic GMOs foods are regulated as "novel foods"[499] and require a pre-market approval. Yet, the practical application of these regulations is different. First, in Canada, labelling is not required[500], even if a survey on the Canadian public opinion has revealed that, as in the US, more than 80% of the population are in favour of labelling GMOs[501]. Secondly, risk assessment required to place GMOs foods on the market, gives producers more control over the information they have to provide.

In particular, Canada has adopted the so-called "trait-based GMO regulation" thereby, since it's the trait that matters, the method of development (i.e. whether the crop was genetically engineered or not) is considered irrelevant. Even if this approach sounds harmless, it has the crucial consequence of leaving control over risk assessment to the applicant, because everything depends on what the applicant chooses to call their trait. "*Imagine you were asked to review the safety of an aircraft, but the manufacturer wouldn't tell you if it was propeller-driven or a jet; likewise, if a submarine was diesel or nuclear powered*"[502].

This approach lies at the core of the 1995 Monsanto's advertising: "*A wide variety of biotechnology products will become available in Canada in the next five years. Monsanto has developed canola that tolerates Roundup herbicide during the growing*

Canada, GM crops are grown on 18% of agricultural land and 25% of arable land, GM varieties account for more than 80% of the grain corn (used for feed); at least 60% of the soybeans; and almost 100% of white sugar beets. These are estimates based on industry and US government data, since the Canadian government does not have statistics on GM crop plantings except for Quebec and Ontario.

[499] In the European Union, the new Regulation (EU) 2015/2283 on novel foods (the new Regulation) is applicable. It repeals and replaces Regulation (EC) No 258/97 and Regulation (EC) No 1852/2001 which were in force until 31 December 2017. The new Regulation improves conditions so that food businesses can easily bring new and innovative foods to the EU market, while maintaining a high level of food safety for European consumers.

[500] The Canadian Food Inspection Agency states: "Labelling is an important means to inform the consumer about product facts. Discussions are underway concerning the various ways to communicate information on products that are derived through genetic engineering" , available at http://www.inspection.gc.ca/plants/plants-with-novel-traits/general-public/overview/eng/1338187581090/1338188593891

[501] ANGUS REID INSTITUTE, *Canadians unclear on definition of "GMOs", but want mandatory GMO labeling anyway*, Immediate Release Canadian Public Opinion Poll, 9 August 2017 Most Canadians (60%) say they "know a little bit about them, but the vast majority of Canadians (83%) say at least some GMOs should be subject to mandatory labeling in grocery stores.

[502] LATHAM J., *The Biotech Industry Is Taking Over the Regulation of GMOs from the Inside*, in *Indipendent Science News*, 19 July 2017, p.1

season and insect-protected potatoes that allow farmers to use fewer pesticides. Other modified crops such as soybeans, alfalfa, corn, flax and tobacco will become available to Canadian farmers in the near future. Canadian consumers will also enjoy imported biotechnology products, such as better-tasking, longer-lasting tomatoes that will be available year-round."[503]. Twenty years later, three of these eight GM foods and crops are on the market in Canada.

A more recent example of this fast-track approval is the *AquAdvantage*[504] Salmon, the first approved genetically modified animal for human consumption[505]. In May 2016, Health Canada and the Canadian Food Inspection Agency (CFIA) approved the sale of this GM fish and by August 2017, almost 4.5 tonnes of GM salmon have been sold in Canada[506].

Yet, since labelling is not compulsory, and the producer has not opted for the voluntary label, "*Canadian consumers have been consuming GM salmon without their knowledge*"[507]. Obviously civil society organizations[508] have challenged this approval before the Court since it "*runs contrary to many of the causes organizations have championed over the years: promoting healthy local food, protecting wild salmon, demanding openness and transparency in government decision-making, ensuring thorough risk assessments as part of environmental approvals*"[509].

---

[503] Monsanto, *Answers to questions food industry groups often ask us about biotechnology*, 27 November 1995

[504] AquaBounty is a biotechnology company focused on enhancing productivity in the aquaculture market

[505]Company researchers have added a growth hormone gene from the Chinook salmon as well as an on-switch gene from the ocean pout, a distant relative of the salmon, to a normal Atlantic salmon's roughly 40,000 genes. Salmon normally feed during the spring and summer, but when the on-switch from the pout's gene is triggered, they eat year-round. They grow twice as fast as natural salmon.

[506] GALLENOS J., *About 4.5 tonnes of GMO salmon consumed in Canada so far, company says*, in *The Washington Post*, 4 August 2017

[507]TREAT S., *CETA, Regulatory Cooperation and Food Safety*, IATP, Greenpeace and Canadian Centre for Policy Alternatives (CCPA), 21 September 2017, p. 3

[508] In particular, Nova Scotia's Ecology Action Centre and British Columbia's Living Oceans Society

[509] COOK J., SHARRATT L., *GM Salmon Swim to Court*, in *Food Secure Canada, News and Media*, available at *https://foodsecurecanada.org/resources-news/news-media/gm-salmon-swim-court*

Among these concerns the crucial one is the following: the Canadian government is receiving 10% royalties from sales of the GM salmon, on the basis of a $2.8 million-dollar grant-agreement between the company AquaBounty and the federal government Atlantic Canada Opportunities Agency.[510] Moreover, after this case, also the Canadian parliamentary Standing Committee on Agriculture and Agri-Food issued to the government several recommendations: to strengthen risk assessment, including a need to assess the long-term system-wide risks of each GM product, to create systems for tracking and tracing all GM organism and to impose mandatory labelling of all GM foods[511]. None of these recommendations has been followed so far.

Therefore, since the aim of CETA is to boost Canadian exports (salmons included), the fear of European consumers is the risk that GM salmon may enter European market even if it is not authorized to do so. In fact, Canada doesn't provide for a system of labelling and traceability equivalent to the European one and on the other it would be infeasible to test each import of Canadian salmon and therefore to detach GM fishes[512].

This case makes evident two crucial challenges that CETA has to face and that will be discussed in the next paragraphs. First, to reconcile the EU and the Canadian view over risk assessment, without affecting the European precautionary principle (which lies at the core of the GM regulations, of the ban of growth promotion drugs, such as growth hormones and antibiotics)[513]. On the other, to prevent the Canadian government, allied with agribusiness and industries, from "undermining European food safety standards through CETA's regulatory cooperation measures"[514].

---

[510] Canadian Biotechnology Action Network (CBAN), *Canadian Government Receiving Royalty Payments from the Sale of Genetically Modified Salmon,* March 2018

[511] House of Commons- Standing Committee on Agriculture and Agri-Food, *Genetically modified animals for human consumption*, Evidence - AGRI (42-1) - No. 22 , December 2016

[512] IATP EUROPE, GREENPEACE NETHERLANDS, *European food and agriculture standards under threat*, 20 September 2017, p. 1, available at https://www.iatp.org

[513] For a general overview see XING L., *Surprise under the table: Inspirations from the Canada-EU CETA for Enhancing Global Agri-Environment by FTAs*, in *Asper Review of International Business and Trade Law*, Vol. 13, 2013,p. 211-240

[514] See note 507, p.7

2.2.3 CETA Trade-facilitating tools: equivalence of standards and regulatory cooperation

At the heart of CETA, several trade-facilitating tools are provided to align standards so that they are as similar as possible: mutual recognition, equivalency and regulatory cooperation are among the main ones.[515] The important premise for this discussion is that different national regulatory systems, including regulations, standards and conformity assessment procedures, may cause impediments to trade.[516] In the food sectors, regulatory differences may exist as a result of variations in taste, technology, resources, income level, administrative culture, risk assessment, societal goals or even by chance.[517]

Underlying equivalency and mutual recognition is the assumption that even different regulations, may achieve the same policy goals (e.g. in relation to health and food quality) and this is why "*agreements involving equivalence assessments make it possible to maintain distinct national regulatory measures while at the same time removing the measures' trade restrictive effects*" [518] .

As already explain in the first Chapter, the WTO SPS Agreement calls upon Contracting Parties to recognize the equivalency of measures as far as "the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of sanitary or phytosanitary protection"[519]

---

[515]COUVREUR A., *New Generation Regional Trade Agreements and the Precautionary Principle: Focus on the Comprehensive Economic and Trade Agreement (CETA) between Canada and the European Union*, in *Asper Review of International Business and Trade Law*, Vol. 15, p. 280

[516] For a general overview on trade-facilitating tool in the WTO and their rationale see SYKES A.O., *Product Standards for Internationally Integrated Goods Markets*, Washington, D.C.: The Brookings Institution, 1995; POLLAK M., SHAFFER G., *Transatlantic Governance in the Global Economy*, Rowman & Littlefield Publishers, 2001; TREBILCOCK M. J., *Trade Liberalization and Regulatory Diversity*, Paper presented at the Third Annual EnviReform Conference, Toronto, 8 November 2002, available at http://www.library.utoronto.ca

[517]SYKES A. O, *The (Limited) Role of Regulatory Harmonization in International Goods and Services Markets*, in *Journal of International Economic Law*, 1999, Vol.2, Issue 1, p. 49

[518] VEGGELAND F., ELVESTAD C., *Equivalence and Mutual Recognition in Trade Arrangements-Relevant for the WTO and the Codex Alimentarius Commission*, NILF-report 2004-9, Norwegian Agricultural Economics Research Institute (NILF), 2004, p.8 avaiable at www.regjeringen.no/ Products coming from one State needs only to comply with the standards of that State, without being required to comply also with another set of rules, avoiding additional costs for producers.

[519] Article 4.1 SPS Agreement

and to "conclude bilateral and multilateral agreements on recognition of the equivalence"[520].

The CETA provides for a similarly-worded provision on equivalence[521], including a list of measures that have to be recognized[522]. Yet, these rules seeking to declare very different food safety standards as "equivalent" have been subject to several concerns, due to the potential threat to the level of protection of health and consumers that the implementation of these rules may have.[523]

This is why it is strongly belied, in the context of both TTIP and CETA, that "concepts such as mutual recognition or equivalence must be handled carefully, otherwise it could lead *de facto* in the long term to deregulation".[524] Thus, the main fear is that, once a mutual recognition agreement is signed, Canadian weak food safety or GMOs standards could be declared equivalent to the European ones, allowing currently banned foods to be imported into the EU.[525]

Yet, when it comes to European standards based on the precautionary principle, the situation is different. As already said, the defining criteria of equivalency, is the existence of the same level of protection of a public good on both side of the Atlantic.[526] It's therefore undeniable that, by definition, invoking a precautionary approach, means providing a higher level of protection. Thus, the result is that at least in theory, the

[520] Article 4.2 SPS Agreement
[521]CETA Chapter five "Sanitary and Phytosanitary measures" Article 5.6 "The importing Party shall accept the SPS measure of the exporting Party as equivalent to its own if the exporting Party objectively demonstrates to the importing Party that its measure achieves the importing Party's appropriate level of SPS protection"
[522] Measures for which the equivalency is recognized are listed under Annex V of the SPS Chapter
[523]BERGKAMP L., KOGAN L., *Trade, the Precautionary Principle and Post-Modern Regulatory Process*, in *European Journal Risk Regulation*, 2013, p. 493-494
[524] The European Consumer Organization (BEUC), *Optimising Regulatory Coherence in TTIP: Need to Focus on Regulation, Not Regulations*, 2005, p. 1-9 For instance, if the EU were to recognise Canadian and American rules on chemical-based meat washes, as equivalents to EU rules, which allows only water, the EU food hygiene legislation would be weakened.
[525] TREAT S., *CETA, Regulatory Cooperation and Food Safety*, IATP, Greenpeace and Canadian Centre for Policy Alternatives (CCPA), 21 September 2017, p.5
[526] See note 515, p. 281

recognition of equivalence should be denied for those Canadian measures which do not incorporate the precautionary principle.[527]

However, the CETA SPS Annex 5-E, Section A, provides that when Canadian and the EU requirements differ in some features, it is the "the responsibility of the exporter to ensure that the products meet the food safety criteria of the importing country"[528]. The result of this provision is that Canadian farmers will still have to comply with EU rules, adjusting their products to fulfil EU food safety standards.[529] That said, the more regulatory divergence is at stake, the more equivalence of systems is hard to be achieved.[530]

Moreover, Canadian agribusiness are not waiting for CETA's ratification to advance their deregulatory aims, especially when considering that TTIP negotiations stalled and Canadian companies will be positioned to take advantage of preferential access over the U.S. competitors in the large European market[531]. Regarding meat, for instance, worth to be mentioned is the statement by Robert Davidson of the Canadian Meat Council, who conditioned the Canada's possibility to take advantage of the import

[527] For example, one should consider the use of growth-hormones for meat products. The *Hormone case* has showed that the EU, by relying on the precautionary principle, provides for a zero-risk level, while in Canada growth hormones have been widely used since the 1960s. See Canadian Animal Health Institute, *Hormone*s, available at https://www.cahi-icsa.ca/hormones

[528] SPS Annex 5-E on Recognition of Sanitary and Phytosanitary measures, Section A, p. 309. One of the equivalent measures comprise the inspection and certification of meat products for human health safety purposes. For Canada: Meat Inspection Act and Regulation, Food and Drugs Act and Regulation. For the EU: Regulation 852/2004 on the hygiene of foodstuffs; Regulation 853/2004 on specific hygiene rules for on the hygiene of foodstuffs; Regulation (EC) 2073/2005 on microbiological criteria for foodstuffs. The Annex provides that "The Canadian and European Union systems are deemed to provide an equivalent level of protection with respect to microbiological requirements. However, the microbiological criteria used by Canada and the European Union for end product monitoring differ in some aspects. For exported products, it is the responsibility of the exporter to ensure that the products meet the food safety criteria of the importing country"

[529] COUVREUR A., *New Generation Regional Trade Agreements and the Precautionary Principle: Focus on the Comprehensive Economic and Trade Agreement (CETA) between Canada and the European Union*, in *Asper Review of International Business and Trade Law*, Vol. 15, p. 282

[530]DE MESTRAL A., *When does the exception become the rule? Conserving regulatory space under CETA*, in *Journal of International Economic Law*, 2015, p.641

[531] Statement by Mr. Brian Kingston (Vice-President, Policy, International and Fiscal Issues, Business Council of Canada), during parliamentary hearings on 17 November 2016, Standing Committee on International Trade, Parliament of Canada, available at http://www.ourcommons.ca/DocumentViewer/en/42-1/CIIT/meeting-45/evidence

quotas in CETA upon the EU "*recognition of equivalence of the Canadian microbial treatments and meat inspection systems*"[532]. Furthermore, for what concerns GMOs, the Soy Canada's Executive Director, complained about the EU delay in approving three GM soy products: "*We are calling on the EU Commission to formally explain why approval of these three products is continuing to be delayed and why its commitments made in CETA negotiations are not being honoured*"[533].

How can negotiations not to be influenced by such pressure?. In this regard, one should not forget that during the TTIP debate, pressured by the US government and the meat industry led the EU to modify one of its main prohibition concerning beef treatment[534].

Also Canada's prior experience in implementing NAFTA makes clear that regulatory cooperation may be a threat to food and agricultural policy.[535] The Canadian Center for Policy Alternatives reports that: "*By invoking the need for harmonization when it suits their purposes, but ignoring it when it does not, successive Canadian federal governments have, hand in hand with business lobbyists, gradually deregulated, under-regulated and moved toward industry self-reporting in order to "reduce the burden" on business*"[536].

Therefore, when regulations cannot be recognized as equivalent, the only possibility left to negotiators is to "carefully shift their policy goals", with the *caveat* that such

---

[532] NEWMARK L., KOVACS M., EU meat industry voices concerns over CETA, in *GlobalMeatNews*, 1 November 2016, available at https://www.globalmeatnews.com . Moreover, the Canadian Meat Council, said that even though "Canada's meat packing and processing industry welcomes European approval of CETA", they are "still awaiting the resolution of important technical barriers, which remain in place even after CETA's signing and that prevent exports of their product to the EU"; see *Canadian Meat Industry Welcomes European Approval of CETA: Awaits Resolution of Technical Barriers*, Press release, OTTAWA, Ontario, 15 February 2017

[533] Radio Canada International, *Canadian GMO soy producers, EU, and the CETA trade deal,* 3 May 2016, available at *http://www.rcinet.ca*

[534] The EU allowed the use of lactic acid to reduce contamination from pathogens on poultry and beef carcasses. See European Food Safety Authority (EFSA), *Decontamination substances,* 26 March 2014

[535] For a general overview on the effect of the North Atlantic Free Trade Agreements on food standards see LILLISTON B., *NAFTA renegotiation: What's at stake for farmers, food and the land,* Institute for Agriculture and Trade Policy, 15 August 2017

[536]TREW S., *From NAFTA TO CETA: Corporate lobbying through the back door*, Canadian Centre for Policy Alternatives, Corporate Europe Observatory, Forum Umwelt und Entwicklung and LobbyControl, 9 February 2017, p. 20

shift "occurs both in favour of the reduction of regulatory barriers as well as the upholding of the level of protection"[537].

It is in this process that regulatory cooperation becomes involved. In fact, it should be remarked that "we are not talking about a traditional free trade agreement such as NAFTA, thereby tariffs on trade in goods and services are eliminated. We are also talking about a second-generation trade agreement where the emphasis is on non-tariff barriers, the main source of trade impediments"[538]. To address them, regulatory cooperation is included in several parts of CETA[539]: first, in the Regulatory Cooperation Charter[540] and then in the SPS and TBT Chapters[541] as well as in the Bilateral Dialogues section. Parties may undertake regulatory cooperation activities on a voluntary basis, meaning that they are bound to try to align their regulations over time.

Yet, for some authors it is mislabelled as voluntary since, if a Party refuses to initiate regulatory cooperation or withdraws from cooperation, it should be prepared to explain the reasons for its decision to the other Party[542] and the entire process is overseen by the Regulatory Cooperation Forum and the CETA Joint Committee.

The fear related to TTIP negotiations comes to the fore even for the CETA: these "living agreements", setting on-going and progressive mechanisms may bring to converging standards to the lowest common denominator[543]. For instance, it has been said that regulatory cooperation may raise the risk that future legislation in the field of biotechnology is from the very outset, influenced by the interests of the biotech

[537]See note 529 , p. 282
[538] LEBLOND P., *The Canada-EU Comprehensive economic and trade agreement: more to it than meets the eye*, in *Policy Option Politiques*, 1 July 2010 p.75
[539]Consolidated CETA text as published by the European Commission on February 2016, available at http://trade.ec.europa.eu/doclib/docs/2014/september/tradoc_152806.pdf
[540] Chapter 21
[541] Chapter 4 and Chapter 5
[542] Article 21.2 (6)
[543] HANSEN-KUHN K., SUPPAN S., *Promises and Perils of the TTIP: Negotiating a Transatlantic Agricultural Market, TTIP Series*, Institute for Agriculture and Trade Policy (IATP), October 2013, p. 4

industry.[544] Furthermore, some scholars evidenced that the commitments "to promote efficient science-based approval processes"[545] and "to establish, when appropriate, a common scientific basis"[546] could constitute a possible attack on the EU precautionary principle[547].

Yet, albeit nor the Regulatory Cooperation Chapter, neither the SPS and TBT Chapters mention such principle, it shall be noted that at least in theory, the actual framework of CETA does not prevent parties "*to incorporate precaution within their risk regulations*"[548]. In fact, as Krstic points out, the level of commitment is very low and "*no obligation exists to align or otherwise reconcile product standards or technical regulations beyond existing WTO obligations*"[549].

Therefore, the CETA voluntary structure does nothing but extending the *status quo* of the precautionary principle's role in the context of risk management, thus revealing the on-going existing gap between the EU and Canada[550]. This is the reason why it has been said that: "the exact contours of the precautionary principle are defined by and contingent upon the context in which the principle is applied"[551], meaning that where

---

[544] THOMSEN B., *CETA's threat to agricultural market and food quality, Working Group for Local Agriculture, 2016, p. 7*

[545] Article 25.2.2(b)

[546] Article 21.4 (n) (IV)

[547] See, inter alia, BANK M., O'BRIEN R., VERHEECKE L., *More cooperation for less regulation." In Making Sense of CETA: An analysis of the final text of the Canada-European Union Comprehensive Economic and Trade Agreement*, 2016, 2nd edition, Berlin and Ottawa: PowerShift, CCPA et al.; SINCLAIR S., TREW S., MERTINS-KIRKWOOD H., Canadian Centre for Policy Alternatives, *Making Sense of the CETA: An Analysis of the Final Text of the Canada-European Union Comprehensive Economic and Trade Agreement*, 25 September 2014. Both underline that the Canadian "risk management" approach to regulating is similar to that used in the US, where most chemicals and products need not be proven safe before entering the market.

[548] See note 529, p. 283

[549]KRSTIC S., *Regulatory Cooperation to Remove Non-Tariff Barriers to Trade in Products: Key Challenges and Opportunities for the Canada-EU Comprehensive Trade Agreement (CETA*), in *Legal Issues of Economic Integration*, Vol. 39, No. 1, 2012 p. 19

[550] As James Mathis evidences, the opposite situation would have been a surprise, since it was expected that "neither Canada, nor EU would act as rule-taker of the other, rather looking for a more balanced approach". See MATHIS J., *Multilateral Aspects of Advanced Regulatory Cooperation: Considerations for a Canada-EU Comprehensive Trade Agreement (CETA),* in *Legal Issues of Economic Integration*, Volume 39, Issue 1, p. 75

[551]PEDERSEN O. W., *From Abundance to Indeterminacy: The Precautionary Principle and its Two Camps of Custom*, in *Transnational Environmental Law*, Volume 3 Issue 2, 2014, p. 325

the approaches are too different, like between the EU and Canada (US as well), a clear harmonization of certain issues is almost an unrealistic settlement.[552]

[552] KERR W. A., HOBBS J. E., *A protectionist bargain? Agriculture in the European Union-CanadaTrade Agreement*, in *Journal of world trade*, 2015, p. 437

2.3 EU-Singapore Free Trade Agreement (EUSFTA) and the EU-Vietnam Free Trade agreement (EUVFTA)

2.3.1 EU as a trading partner of the South-East Asia

After the analysis of the crucial issues at stake between the EU and the other side of the Atlantic, also the European Free Trade Agreements with Southeast Asian countries deserve to be briefly analysed. Even though they are not as problematic as TTIP and CETA for what concerns food law, their relevance in the "Global Europe"[553] strategy is uncontroversial. In the past decades, in fact, globalization of the world's economies has witnessed the emergence of new economic powers and the EU Commission acknowledged that liberalization of trade in services, good, capitals and intellectual property with these countries was as a crucial factor for future economic growth[554].

For what concern the food sector more in detail, the latest monthly trade report of the EU Commission[555], revealed that the value of EU agri-food exports increased by €1 billion between November 2016 and November 2017 to €12.7 billion and that, in terms of markets, the US, Russia and Asia markets remain the most dynamic for EU agri-food export growth[556].

The first Free Trade Agreement, concluded after the entry into force of the Lisbon Treaty has been the EU-Korea FTA (KOREU), signed in 2010.[557] Definitely, it

---

[553] EU Commission, *Global Europe: Competing in the World, A Contribution to the EU's Growth and Jobs Strategy*, Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions, COM (2oo6) 567 final, 4.10.2006

[554] MULLER G., *The EU's Global Europe Strategy and the Liberalization of Trade in Legal Services: The Impact of the EU Free Trade Agreements in Asia*, in *Journal of World Investment & Trade*, Vol. 14, Issue 4, 2013, p. 730

[555] EU Commission, Agriculture and Rural development, *Monitoring EU Agri-Food Trade: Development until November 2017*, 23 March 2018

[556]Looking at product categories, the report reveals that: Wine (EUR +1.25 billion; +12 %), milk powder (EUR +936 million; +26%) and infant food (EUR +809 million; +12 %) exports have been performing very well over the last twelve months. Export performance on a yearly basis also increased significantly by almost EUR 600 million for pet food and for spirits and liqueurs

[557] It was provisionally applied from 1 July 2011 up to its entry into force on 13 December 2015. For an overview on the relevance of this agreement see BOSSUYT F., *The social dimension of the new generation of EU FTAs with Asia and Latin American: Ambitious Continuation for the sake of policy Coherence*, in *European Foreign Affairs Review*, 2009, p. 703 ss. and HORNG D. C., *Reshaping the*

represented a model for the agreements negotiated afterwards, since it is not limited to the provision of mutual removal of tariff barriers, but it contains also rules on non-tariff barriers, in particular in the field of vehicles, electronics, pharmaceutical and medical devices.[558] Moreover, it has been shown that for what concerns the Korean food sector, the trend towards healthier and safer food and beverages is expected "to further continue as Korean consumers in general are very health conscious" and this is a strong opportunity for European products.[559]

For what concerns more in general the Asian region, the 1997 financial crisis of the Asian countries made them change their position on free trade agreements, even if in the period of "regionalism waves" described in chapter 1, they used to maintain a trade policy emphasizing multilateralism in the context of the WTO rules.[560] In the period 2001-2005, in fact, " Asia was responsible for nearly thirty percent of FTAs notified to the WTO.[561] More in particular, negotiations between the European Union (EU) and the Association of Southeast Asian Nations (ASEAN) for the conclusion of a FTA formally started in 2007[562].

Economic relations between the two parties have proven to be mutually beneficial, since on the one hand, the EU is ASEAN's second larger trading partner after China and by far the largest investor and on the other, ASEAN is the EU third largest trading partner after the US and China[563]. Yet, in 2009 negotiations paused and the focus

---

EU's FTA Policy in a Globalized Economy: The case of EU- Korea FTA, in *Journal of World Trade*, 2012, p. 301 ss

[558] RUOTOLO G. M., *Gli accordi commerciali di ultima generazione dell'Unione Europea e i loro rapporti con il sistema multilaterale degli scambi*, in *Studi sull'Integrazione Europea*, 2016, p. 330

[559] *Growing interest in European organic food & beverage products in Asia*, available at https://www.eu-gateway.eu

[560] TEKCE M., ACAR S., *From multilateralism to bilateralism: The impact of free trade agreements on global trade policies*, p. 115, January 2008, available at https://www.researchgate.net

[561] PARK S. H., *Increasing FTA initiatives of East Asia and the World Trading System: Current state of play and policy options for the 21st Century*, in *ASIEN: The German Journal on Contemporary Asia*, vol 100, p. 44

[562]ASEAN countries, belonging to South-East Asia are Vietnam, Laos, Cambodia, Thailand, Myanmar, Indonesia, Malaysia, Singapore, Philippines, East Timor, Brunei. In the same year negotiations started also with India and South Korea

[563] Delegation of the European Union to Vietnam, *Guide to the EU-Vietnam Free Trade Agreement*, p.23, available at http://eeas.europa.eu/archives/delegations/vietnam/

shifted on bilateral FTAs negotiations, considered as building blocks towards a future region-to-region agreement[564]. Th rationale of this evolution lies in the fact that, shortly after negotiations got underway, "the Europeans quickly understood that while the EU negotiated as a genuine bloc, ASEAN did not. When negotiating with ASEAN, at least 11 people were seated at the table, one person from each of the member states plus someone from the ASEAN Secretariat"[565]. Therefore, the EU decided that it would have been easier and with better results, negotiating agreements on an individual basis.

For what concerns Singapore and Vietnam, the European Commission finalised negotiations of a bilateral FTA respectively in October 2014 and in December 2015.[566] Both of them are comprehensive agreements, covering market access for goods, trade in services and establishment, intellectual property rights, technical barriers to trade, sanitary and phytosanitary measures, government procurement, competition policy, sustainable development and dispute settlement mechanism[567]. Even though, as already said, they did not raise issues for what concerns food security as CETA and TTIP did, their main provisions addressing the food sector will be briefly discussed in the next paragraphs.

[564]Negotiations with Singapore and Malaysia were launched in 2010, with Vietnam in June 2012, with Thailand in March 2013, with the Philippines in December 2015 and with Indonesia in July 2016. Negotiations of an investment protection agreement are also under way with Myanmar (Burma).

[565] ELMS D., *Understanding the EU–Singapore Free Trade Agreement in Australia, the European Union and the New Trade Agenda*, Annmarie Elijah, Don Kenyon, Karen Hussey and Pierre van der Eng editors), 2017, by ANU Press by ANU Press, The Australian National University, Canberra, Australia

[566] For an overview on the status of the European FTAs visit http://ec.europa.eu

[567]EU Commission, DG Trade, *Guide to the EU-Singapore Free Trade Agreement and Investment Protection Agreement,* April 2018

2.3.2 The food and beverage sector in the EUSFTA and EUVFTA

From an EU prospective, the FTA with Singapore is expected to be the first free trade agreement with a member of the ASEAN and the second agreement with an Asian country after South Korea.[568] EUSFTA has been negotiated since March 2010 and it's text has been publicly accessible since June 2015.[569] While negotiations on goods and services have been concluded in 2012, those related to investment protection have been completed on October 2014.[570] Singapore is the EU's largest trade partner in Southeast Asia, accounting for one-third of EU trade with the region[571]. Yet, it has very little agricultural land and its agricultural production is small-scale and limited to very few products[572] and this is evidenced by the fact that it is the fifth biggest export market in Asia for EU food and drink exports, with annual exports coming to around €2 billion.[573]

Therefore, since Singapore meets food needs with imports for what concerns the food sector, in the EUSFTA has committed itself to keep the already existing zero duties on EU exports of agri-food products.[574] Moreover, in order to fight against the phenomenon of the Italian-sounding and ensuring the top-quality of European food and beverages, the agreement sets up a system to register geographical indications (GIs)[575] in Singapore, allowing 196 GIs to enjoy levels of protection equal to those existing in the EU.[576]

---

[568] Ministry of Trade and Industry Singapore, *FREE TRADE AGREEMENT BETWEEN THE EUROPEAN UNION AND SINGAPORE (EUSFTA) A guide for Singapore-based companies to understanding the EUSFTA*, 2014, p. 5

[569] Avaiable at http://trade.ec.europa.eu/doclib/press/index.cfm?id=961

[570] The EUSFTA comprises 16 Chapters, one protocol and four understandings

[571] European Commission, DG Trade, *The EU-Singapore agreement explained, 18 April 2018.* Lowers, certain fruit (mainly durians and rambutans), eggs, Vegetables, poultry, pork

[572] Lowers, certain fruit (mainly durians and rambutans), eggs, Vegetables, poultry, pork. n 2016, the EU exported €2.2 billion of agri-food products to Singapore, more than double 10 years earlier. Today, Singapore is the EU's 5th largest agri-food export market in Asia and its 15th worldwide.

[573] See note 568, p. 10

[574] Chapter 2-Annex 2-A, Article 1: "All customs duties by a Party on goods originating in the other Party shall be eliminated as from the date of the entry into force of this Agreement, except as otherwise provided in the respective Party's Schedules included in this Annex"

[575] GIs are distinctive food and drink products from specific regions in the EU

[576] This includes for instance the well-known Bordeaux wines, Parma ham, Champagne and Bayerisches Bier. To examine the complete list of the 196 protected GIs, see Chapter 10 Annex *List of names to be*

For what concerns food safety, Chapter 5 is of crucial important since its objective is "to protect human, animal or plant life or health in the respective territories of the Parties, while facilitating trade in the area of sanitary and phytosanitary measures"[577].

Moreover, in order to ensure the effective implementation of this Chapter, Article 5.8 provides that "the importing Party shall have the right to carry out verifications at any time, including: (a) through verification visits to the exporting Party, to verify all or part of the inspection and certification system of the exporting Party's competent authorities, in accordance with the relevant international standards, guidelines and recommendations of the Codex Alimentarius; and (b) by requiring information from the exporting Party about its inspection and certification system and obtaining the results of the controls carried out thereunder".

Therefore, this mechanism will allow EU Member States to export to Singapore food products, such as meat products thanks to verifications and recommendations of their competent authorities that they fulfil Singapore's sanitary and phytosanitary requirements. The agreement also safeguards the EU's right to apply European standards to all goods sold in Europe. Therefore, imports of food products from Singapore to the EU, still have to satisfy technical standards, consumer safety requirements, rules on animal and plant health and hygiene, food safety regulations[578] provided by the EU food law.

applied for protection as geographical indications in the territory of the parties. The agreement will be effective as far as the process of recognition and protection of the GIs will be completed. On the issue, see inter alia, DI MAMBRO A., *Accordo UE-Singapore, tutelate DOP e IGP*, in *Italia Oggi*, 22 October 2014, RAFFIOTTA E. C., *La protezione multilivello delle tipicità agroalimentari tra diritto globale e legislazione nazionale*, in *Rivista di diritto pubblico italiano, comparato, Europeo,* December 2016, p. 1-13, GALLI C*., Globalizzazione dell'economia e tutela delle denominazioni di origine dei prodotti agro-alimentari*, in *Diritto Industriale*, 2004, p. 60 e ss., BORRONI A., *La protezione delle tipicità agroalimentari, uno studio di diritto comparato*, Napoli, 2012, p. 13 ss., PETRELLI L., *Prodotti DOP, IGP e certificazione*, in *Rivista di diritto Agrario*, 1999, p. 72 e ss.

[577] Chapter 5 on Sanitary and Phytosanitary measures, Article 5.1

[578] Chapter 5, Article 5.7 on Importing requirements par. 1 "The import requirements of a Party shall apply to the entire territory of the other Party", par. 2 "The exporting Party shall ensure that products exported to the importing Party meet the sanitary and phytosanitary requirements of the importing Party"

Following the conclusion of the EUSFTA in 2014, negotiations with Vietnam were competed in December 2015.[579] Before this FTA, Vietnam enjoyed preferential access to the EU, thanks to the General System of Preferences which the EU has granted to foster trade with developing countries[580], allowing Vietnamese products to be imported into the EU duty-free or with reduced duties.

Yet, since this mechanism did not ensure a reciprocal preferential access to Vietnam on the part of the EU, its limitations from an economic prospective are crystal clear and therefore the implementation of the EUVFTA was though to be a better solution. This is even more true considering that in 2014, Vietnam became the EU's second biggest trading partner in ASEAN after Singapore and ahead of Malaysia, with trade between the EU and Vietnam worth € 38 billion[581]. EU Trade Commissioner Cecilia Malmström, in fact, underlined that: "the agreement will unlock a market with huge potential for EU firms. Vietnam is a fast-growing economy of more than 90 million consumers and its market offers numerous opportunities for the EU's agricultural, industrial and services exports"[582].

For what concerns the food sector, Vietnam will open its market for several EU food products, allowing European high-quality exports to reach the Vietnamese consumers.[583] As well as the EUSFTA, 171 European food and drink products from a

[579] The same month negotiations with the Philippines for an FTA were launched

[580] Delegation of the European Union to Vietnam, *Guide to the EU-Vietnam Free Trade Agreement*, p.22, available at http://trade.ec.europa.eu

[581] Ibid, p. 3, Vietnam's key export items to the EU include, electronic products, textiles, clothing, but also food products such as coffee, rice and seafood.

[582] EU Commission, *EU-Vietnam Free Trade Agreement Now Available Online*, 1 February 2016, available at http://trade.ec.europa.eu

[583]EU Commission, Memo, *EU and Vietnam reach agreement on free trade deal*, 4 August 2015. Wines and spirits will be liberalised after 7 years, frozen pork meat will be duty free after 7 years, beef after 3 years, dairy products after a maximum of 5 years and food preparations after a maximum of 7 years, Chicken will be fully liberalised after 10 years. Only some sensitive agricultural products will not be fully liberalised, but the EU has offered access to Vietnamese exports via tariff rate quotas (TRQs): rice, sweet corn, garlic, mushrooms, sugar and high-sugar-containing products, manioc starch, surimi and canned tuna.

specific geographical origin will enjoy recognition and protection on the Vietnamese market – at a comparable level provided by to the EU legislation[584].

This agreement, as well as the EUSFTA, does not only reduce custom duties[585], but it also addresses non-tariff barriers. Again, the main tool to regulate the food sector is the chapter on Sanitary and Phytosanitary Measures, whose aim is, *inter alia*, to "enhance practical implementation of the principles and disciplines contained within the SPS Agreement" of the WTO system[586]. Therefore, using the latter Agreement as a model and in order to address the specific needs of Vietnam linked to its status of developing country, provisions on "Equivalence of standards", "Technical Assistance, Special and Differential Treatment" are included[587].

Last but not the least, two innovative principles have been included: the principle of regionalization and the recognition of the EU as a single entity. According to the first one, "*The Parties recognise the concept of disease-free areas, areas of low disease prevalence, and compartmentalisation in accordance with the SPS Agreement and OIE[588] standards, guidelines or recommendations*"[589]. Therefore, should a disease affect a limited area, this provision will allow Vietnam to adopt restrictive measures

[584] Again, this means that in Vietnam the use of GIs such as Champagne, Parmigiano Reggiano cheese, Rioja wine, Roquefort cheese or Scotch Whisky will be allowed for products imported from the European regions where they traditionally come from. The full list of the EU and Vietnamese GIs is included in Chapter 12 on Intellectual Property, Annex GI – I

[585] Chapter 2, Annex 2-c: Reduction and/or elimination of customs duties. Both parties will dismantle more than 99% of tariffs over 7 years (EU) and 10 years (Vietnam) respectively.

[586] Chapter 7, Article 2 "Objectives"

[587] Article on Equivalence, par.1 "The Parties recognise that the application of equivalence that principle set down in Article 4 of the SPS Agreement is an important tool for trade facilitation and has mutual benefits for both exporting and importing countries...", par.2 "The importing Party shall accept the sanitary and phytosanitary measures of the exporting Party as equivalent if the exporting Party objectively demonstrates that its measures achieve the importing Party's appropriate level of sanitary and phytosanitary protection…" Article on Technical Assistance and Special and Differential Treatment par.1 "Technical assistance should be provided to address specific needs of Vietnam, to comply with sanitary and phytosanitary measure(s) regulated by EU Party including food safety, plant health and animal health, and the use of international standards"

[588] World Organization for Animal Health

[589] Article on Measures linked to animal and plant health, par. 1; Moreover, par.2 of the same provision states that "The Parties also recognise the official animal health status as determined by the OIE" The rationale of this innovative provision is "to push Vietnam to drop any barriers related to BSE (and other diseases for which the OIE grants an official status), except when aligned with OIE standards" see note 255, p. 40

only with regard to products coming from the area itself and not beyond. According to the second principle, Vietnam has accepted the commitment to apply to alike products coming from all 27 Member States the same import requirements (like food safety ones), without setting different standards for each State as it happened in the past[590].

In conclusion, these are the relevant aspects concerning food law of these FTAs, which, if implemented correctly may have a positive economic impact for the EU agri-food market.[591] However, sometimes it may happen that even if trade negotiations with a trade partner have been concluded, agreements have not been either signed or ratified yet, and this is the case of both the EUSFTA and EUVFTA.[592] The ratification process, in fact, has been delayed owing to the request for an advisory opinion submitted by the Commission to the ECJ concerning the EUSFTA.[593] As it will be discussed in the next paragraph, the Court argued "*that some aspects of the EU-Singapore FTA, which is similar to the Vietnam FTA, are 'mixed competences', meaning that the FTA as it stands will have to be ratified not only by the EU but also by all Member States*."[594]

[590] EU Commission, Fact sheet, *Facts and figures: Free Trade Agreement between EU and Vietnam*, 4 August 2015, p. 6

[591] EU Commission, DG Trade, *The economic impact of the EU - Singapore Free Trade Agreement*, September 2013; ARMANOVICA M., *EU-Vietnam economic and trade relations*, Policy Department, Directorate- General for External Policies, European Parliament, September 2012. For an overview on the impact of the EUSFTA on Vietnam see BINH DUONG N., Vietnam-EU Free Trade Agreement: Impact and Policy Implications for Vietnam, Working Paper No. 07/2016 | June 2016

[592]To check the current state of play of EU negotiations and agreements visit http://ec.europa.eu/trade/policy/countries-and-regions/negotiations-and-agreements/ The agreements will be subject to legal revision by the Commission and then transmitted to the Council of the European Union and to the European Parliament.

[593]Official Journal of the European Union, Opinion 2/15: Request for an opinion submitted by the European Commission pursuant to Article 218(11) TFEU, 10 July 2015

[594]European Parliamentary Research Service, RUSSEL M., *EU-Vietnam free trade agreement*, Briefing, International Agreements in Progress, February 2018

The Commission and Council are now considering whether to modify the agreement so that parts of it can be ratified more speedily by the EU alone

2.1.1 The Court of Justice's Advisory Opinion 2/15- the EUSFTA as a "mixed" or "EU only" agreement

As already said in the first Chapter[595], the Lisbon Treaty has introduced relevant changes for what concerns the EU exclusive competence regarding trade agreements.[596] The key TFEU provisions at stake are Article 207 (1) in conjunction with Article 3 (1) thereby, the conclusion of tariff and trade agreements relating to foreign direct investment has been included in the common commercial policy.[597]

Yet, the scope of this competence has created, among scholars, a long-standing debate focused on two main issues.: the meaning of "foreign direct investments"[598] and the EU competence on the regime governing dispute settlement between investors and States included in the EU investment agreements[599]. Yet, these concerns have not prevented the Commission to undertake negotiations of FTA with third countries, such as Canada, Singapore and Vietnam.[600]

It's in this context that the advisory opinion delivered by the ECJ on 16 May 2017 shall be included[601]. On July 2015, in fact, "*in the interest of all parties, the Commission wanted to get legal clarity on the issue and submitted this request concerning the allocation of competences between the EU and the Member States in the EU-Singapore*

[595] See Chapter 1, par. 1.3.3
[596] DOLLE T., BRUNO G., *Mixed Feelings about Mixed Agreements and CETA's Provisional Application*, in *European Journal of Risk Regulation (EJRR*), Vol. 7, Issue 3, 2016, p. 617
[597]Article 207 par.1 "The common commercial policy shall be based on uniform principles, particularly with regard to changes in tariff rates, the conclusion of tariff and trade agreements relating to trade in goods and services, and the commercial aspects of intellectual property, foreign direct investment, the achievement of uniformity in measures of liberalisation, export policy and measures to protect trade such as those to be taken in the event of dumping or subsidies. The common commercial policy shall be conducted in the context of the principles and objectives of the Union's external action"
[598] MULLER-GRAFF P. C., *The Common commercial Policy Enhanced by the Reform Treaty of Lisbon*?, in DASHWOOD A., MARESCEAU M., *Law and Practices of EU External Relations-Salient Features of a Changing Landscape*, Cambridge, 2008, p. 190
[599]REINISCH A., *The division of Powers between the EU and its Member States after Lisbon*, in BUNGENBERG M., GRIEBEL J., HINDELANG S., *European Yearbook of International Economic law*, Berlin, 201, p. 52-53
[600]European Commission, *Towards a Comprehensive European International Investment Policy*, COM (2010) 343 final
[601] European Court of Justice, Advisory Opinion 2/15, 16 May 2017, ECLI:EU:C:2017:376

trade agreement".[602] On the one hand, the Commission and the Parliament claimed that the Agreement could be concluded by EU alone, on the other, Member States[603] and the Council contended that it had a 'mixed' nature.

The Court hold that EUSFTA cannot, "in its current form, be concluded by the EU alone"[604], because "the envisaged agreement falls within the exclusive competence of the European Union, with the exception of those provisions which fall within a competence shared between the European Union and the Member States"[605]. In particular, only in respect of two aspects of the agreement the EU has not exclusive competence: the so-called portfolio investments[606] and the Investor-State Dispute Settlement mechanism[607]. For sure, the EU institution welcomed this opinion because the issue "is not about winning or losing but about legal clarity and stability on competences and responsibilities for the future of EU trade agreements".[608]

Yet, in the light of this opinion, the Commission, will be obliged to look for different options when it comes to trade and investment agreements[609]. It may decide to ratify the agreement as a "mixed" one, by keeping it in its current form, or to transpose the provisions addressing non-direct foreign investments and the investor-state dispute settlement mechanism into another agreement, in order to allow the EU only to ratify the remaining part of the FTA, which fall under its exclusive competence.[610]

---

[602]EU Commission, Factsheet, *The Opinion of the European Court of Justice on the EU-Singapore Trade Agreement and the Division of Competences in Trade Policy*, September 2017, p. 1

[603] Written observations to the Court were submitted to the Court by all Member States, except Croatia, Estonia, Sweden and Belgium

[604] Court of Justice, Press Release No 52/17, Luxemburg, 16 May 2017

[605] Advisory Opinion, par.305

[606] Ibid par. 243. They are indirect investments thereby the investor has no intention to influence the management of the investment, meaning the strategic choice and control of an undertaking. They are usually short-term investments and a weaker link with the economy of the Host State exists. See OCSE, Benchmark Definition of Foreign Direct Investment, 2008, par.11, 29

[607] Advisory Opinion, par. 293. The rationale of this choice lies in the fact that "such a regime removes disputes from the jurisdiction of the courts of the Member States" (par. 292) and therefore their consent is needed

[608] See note 602, p.4

[609]MONTANARO F., *Il parere 2/15 della Corte di Giustizia dell'Unione Europea e il futuro della politica commerciale dell'Unione*, in *Osservatorio Costituzionale*, Fasc. 3/2017, 10 September 2017, p.10

[610]European Parliamentary Research Service, RUSSEL M., *EU-Vietnam free trade agreement*, Briefing, International Agreements in Progress, February 2018, p. 8

Obviously, opting for the first option will considerably prolong the period of time for the entry into force of the EUSFTA as well as of the EUVFTA, and the CETA is, of course, the proof of the longer ratification process which "mixed" agreement require[611].

The present chapter has made clear the implications that this new generation of FTAs may have on the rigid EU food safety standards and on the exportations of the EU top-quality foods. While, FTAs with Vietnam and Singapore are likely to produce a remarkable increase of wealth for the EU agri-food market, TTIP and CETA seem to represent more a threat that an opportunity for the safety of the European food market.

As underlined in Chapter 1, par.3 it is the stagnation in WTO negotiations the reason behind the current trend in favour of this kind of bilateral and regional trade agreements. They are considered as "more flexible and effective tools for the establishment of harmonized trade standards"[612].

However, albeit this positive aspect, the common feeling expressed by the public opinion of the States involved is that, for what concerns food safety standards, these bilateral and regional negotiations may be going in the wrong direction. On the one hand, these agreements have been identified as an important opportunity to solve regulatory divergence by providing indirect legal tools such as regulatory cooperation, harmonization and mutual recognition of standards.[613] On the other, most of the truly debated food issues seem to remain unaddressed and the case of the use of biotechnology in the food sector, of growth hormones and of animal cloning are clear examples in this regard.

It is true that regulatory divergence imposes a large cost on trade, but sometimes the existing gap between negotiating Parties may be too wide to be overcome. This is the

[611] MORGAN S., *Future of EU trade deals in doubt after Singapore ruling*, in *EURACTIV*, 22 December 2016, available at https://www.euractiv.com
[612] PETROVETS K. A., *Moving towards harmonization of food safety standards: Role of the TTIP and TTIP Agreements*, in *Journal of Food Law and Policy*, 2016, p. 133
[613] COUVREUR A., *New Generation Regional Trade Agreements and the Precautionary Principle: Focus on the Comprehensive Economic and Trade Agreement (CETA) between Canada and the European Union* in, *Asper Review of International Business and Trade Law*, Vol. 15, p. 271

reason why some authors are still claiming that the new free trade agreements will not be able to reconcile divergent regulatory schemes, especially when it comes to the precautionary principle in the transatlantic trade relationship.[614] This is why it has been said that "*sometimes one side is to blame for the divergence. Other times it is simply two countries regulating the same issue in different ways; where the differences are too entrenched, it will be hard to find solutions*"[615].

Therefore, the next Chapter will try to answer two main questions. The first one is about "whether or not, for the quality of EU food standards, these transatlantic agreements represent a race to the top or a race to the bottom"[616]. The second one concerns the potential that "*the new generation trade agreements contain to enhance a shared understanding of the precautionary principle*"[617] and to produce a global improvement of food security standards.

[614] See, inter alia, KRSTIC S., *Regulatory Cooperation to Remove Non-Tariff Barriers to Trade in Products: Key Challenges and Opportunities for the Canada-EU Comprehensive Trade Agreement (CETA)*, in *Legal Issues of Economic Integration*, Vol. 39, No. 1, 2012, p. 3-28

[615] LESTER S., BARBEE I., *The challenge of cooperation: Regulatory Trade Barriers in the Transatlantic Trade and Investment Partnership*, in *Journal of International Economic Law*, 2013, p. 856

[616] BONORA G., *Sul difficile nodo della carne trattata con ormoni nel "Transatlantic trade and investment partnership (TTIP)*, in *Rivista di diritto agrario*, 2016, fasc. 1, pt. 1, p. 137

[617] COUVREUR A., *New Generation Regional Trade Agreements and the Precautionary Principle: Focus on the Comprehensive Economic and Trade Agreement (CETA) between Canada and the European Union* in, *Asper Review of International Business and Trade Law*, Vol. 15, p. 287

Chapter 3)

Free trade agreements, global governance of food safety standards and the role of the EU: between multilateralism and bilateralism

A general overview

Chapter 2 has shown how food safety is at the crossroad of political, economic and cultural issues. The WTO disputes examined, in fact, have made clear the main reasons laying at the core of the international debate concerning food safety standards: the different assessment of scientific evidences concerning risk, the divergent cultural perceptions and consumer preferences.

Along with these issues, one should not underestimate how the ongoing industrialization of food products and the development of supply chains linking producers and consumers from all over the world are likely to increase related food safety risks. This situation clearly illustrates "*the urgent need to find integrated solutions at different levels, since the international, regional and national scenario proved to be strictly connected in identifying the many different aspects of a figure (food law) which is multi-faced and complex but at the same time fundamental for present and future generations*"[618].

Therefore, to address this global matter, more and more governments worldwide are seeking to develop tools of international cooperation in the form of comprehensive bilateral free trade agreements (FTA) or in more restricted mutual recognition agreements (MRA)[619]. The rationale of this approach lies in the limits of the WTO's multilateral trading system where food safety is relevant only as far as is trade related

[618]RICCI C., *International law as a meta-framework for the protection of the right to food*, in LUPONE A., RICCI C., SANTINI A. (eds.) *The right to safe food towards a global governance*, Torino, Giappichelli, 2013, p. 10

[619] This work focuses only on the EU FTAs. For a general overview on this second type of agreements see KERBER W., VAN DER BERGH R., *Mutual recognition in the global trade regime: lessons from the EU experience*, in LIANOS I., ODUDU O. (eds.) *Regulating trade in services in the EU and the WTO: trust, distrust and economic integration*, Cambridge University Press, 2012, p. 121-124

and where, in the balancing between economic and non-economic issues, trade values have almost always ended up prevailing.

This Chapter is made up of four paragraphs. The first one, focusing on the failure of TTIP negotiations, will show how this Partnership would have represented a crucial opportunity to bridge the US and EU approaches to risk assessment and risk management, by reconciling the brave American cost-benefit analysis and the cautious European precautionary principle. The second paragraph will focus on the free trade agreement between EU and Canada (CETA), seeking to examine the role that multinational corporations will acquire in the framework of regulatory cooperation. Since their aim is to maximize profits, the risk that food safety standards and procedures, representing additional costs for producers, may be targeted as "unnecessary barriers to trade" is less than hypothetic. The third paragraph will try to stress out the limits of the WTO system in addressing food safety issues and to verify whether the FTAs analyzed in Chapter 2 are able to overcome such limits and to produce positive impacts on the global governance of food standards. The last one contains a comprehensive evaluation of the Regulation No 178/2002. It demonstrates the efficiency, effectiveness and coherence of this system, while underlying that CETA, TTIP and other current and future FTAs may represent a vehicle to make EU food law a model worldwide.

The underling idea of this Chapter is that FTAs do not have to bridge all the existing regulatory divergences, but rather to find practical solutions to solve problems in sensitive sectors like the food one. "*A transparent, inclusive and open process that involves all stakeholders, from business to consumers, is a good model for achieving regulatory cooperation going forward*"[620].

[620]LESTER S., BARBEE I.., *The Challenge of Cooperation: Regulatory Trade Barriers in the Transatlantic Trade and Investment Partnership* in *Journal of International Economic Law*, Volume 16, Issue 4, 1 December 2013, p. 863

3.1 The failure of TTIP negotiations: a missed opportunity to reconcile the American Cost-benefit analysis and the EU precautionary principle in the food sector

Nowadays, owing to Brexit and the provisional application of CETA, the conclusion of TTIP may seem less attractive for the US[621]. On the one hand, they could prefer negotiating an agreement with UK without being forced to comply with the strict European food standards.[622] On the other, USA may pay attention to the concrete results of CETA to understand what it is possible to obtain by negotiating with EU[623]. Moreover, in light of the US Presidential election, the EU trade Commissioner Cecilia Malmström made clear that "*indeed, the victory of Donald Trump has created a degree of uncertainty concerning what his priorities as President will be, and there is reason to believe that there will be an extended pause in the TTIP negotiations*"[624].

As already underlines in Chapter 2, differences between the transatlantic food trade, have diverse backgrounds: political preferences, cultural values and divergent scientific approaches as risk-takers or risk-adverse countries[625].

Yet, as the U.S. Trade Representative Froman emphasized, one of the crucial challenges faced during TTIP negotiations has been the "*historical difference about the appropriate approach to regulation, characterized as a so-called gap between*

---

[621] ALABRESE M., *Gli accordi commerciali mega-regionali e l'elaborazione del diritto agroalimentare* in *Rivista di diritto agrario,* fasc. 1, 2017, pt.1 p. 152

[622]In this regard, see the statement by Ambassador Froman on the UK Referendum: "The importance of trade and investment is indisputable in our relationships with both the European Union and the United Kingdom. The economic and strategic rationale for T-TIP remains strong. We are evaluating the impact of the United Kingdom's decision on T-TIP and look forward to continuing our engagement with the European Union and our relations with the United Kingdom", available at https://ustr.gov/

[623] BONARDI B., *TTIP, negoziati ufficialmente congelati dopo elezione di Trump. La Commissione Ue prende atto della contrarietà agli accordi commerciali internazionali,* in *IlFattoAlimentare*, 17 November 2016, avaiable at *http://www.ilfattoalimentare.it;* American multinational corporations, which have their seat in Canada, may enjoy the free-market regime that CETA will create, without TTIP needed anymore.

[624] Cecilia Malmström, EU Commission-Blog post, *Signing trade agreement with Ecuador*, 11 November 2016

[625] FUNG S., *Negotiating Regulatory Coherence: The Costs and Consequences of Disparate Regulatory Principles in the Transatlantic Trade and Investment Partnership Agreement Between the United States and the European Union*, in *Cornell International Law Journal*, 2014, p. 467

Europe's preference for the precautionary principle and the United States' focus on cost-benefit analysis"[626]. This assumption has been proved not only by the fact that EU and US often opt for different methods in legally shaping their food security, but also by the "*on-going refusal to recognize the validity of each other's approach*"[627]. Yet, both Forman himself and other scholars also acknowledge that it would be an oversimplification, if not a caricature of each regulatory principle, a strict reliance on this distinction[628].

Forman argues that "*it is a caricature to suggest that when Europe only takes regulatory action based on the precautionary principle, in other words without 100 percent scientific certainty, that it prohibits an activity. Since science is rarely definitive, under this scenario, all productive activity would cease. Similarly, it is a caricature to suggest that the U.S. bases its regulations solely on cost-benefit analysis, and that it does not take qualitative factors into consideration, such as dignity, fairness and equity*"[629].

Other commentators, like Morrall III, show that albeit the existence of some differences in the regulation of certain food products, the overall risk of both systems is similar and that it is the way in which regulatory schemes are implemented that creates the gap.[630]

---

[626] U.S. Trade Representative Michael Froman, Remarks on the United States, the European Union, and the Transatlantic Trade and Investment Partnership, 30 September 2013, available at https://ustr.gov/about-us/policy-offices/press-office/speeches/transcripts/2013/september/froman-us-eu-ttip

[627]NUTTALL T., *Charlemagne: Ships That Pass in the Night*, in *THE ECONOMIST*, 13 December 2014, http://www.economist.com; See also KNOLL K., *Safeguarding Consumer Rights and Protection in TTIP*, in CARDOSO D. (eds.) *THE TRANSATLANTIC COLOSSUS: Global contributions to broaden the debate on the EU-US Free Trade Agreement*, 2013, thereby "the U.S. views newer and more scientific methods as safer, whereas the EU, typically wary of hidden dangers in adopting newly developed technologies to food cultivation, places greater trust in more traditional practices"

[628] See note 621, p. 452

[629] See note 623

[630] MORRALL III J.., U.S. Chamber of commerce, *determining compatible regulatory regimes between the ES and the EU*, in *Advancing Transatlantic business*, 2011, p.3 "U.S. and EU regulators strive for similar regulatory outcomes is well-established; a detailed study of 3,000 risk-reducing regulatory decisions in the U.S. and EU shows that overall risk stringency is about the same, while divergences stem largely from protectionism and local rent-seeking. Other studies cited herein highlight the existing and prospective overlap especially in the areas of automotive safety, chemicals and pharmaceuticals.

Such dichotomic prospective, in fact, is not able to grasp the current dynamism of international relations, which in a globalized market, leads more and more to the thinning of cultural differences.[631] On the one hand one should note that even in the EU, critical consumers who pay attention to the quality of food products still represent an *èlite*[632]. On the other hand, even on the part of US, some initiatives in the food sector have been undertaken; for what concerns GMOs regulations, proposals on a special labelling system and on the adoption of a pre-market approval mechanism, have been undertaken by several US states[633]. Regarding food law more in general the new Food Safety Modernization Act, entails some contact points with the EU General Food Law[634].

Yet, after looked at this faint approximation of the two Atlantic sides, it should be asked whether or not TTIP impose necessarily a clear and definitive choice between their different approaches to food safety. In fact, some critics argue that for making regulatory and deregulatory decisions "*cost-benefit analysis (CBA) and the precautionary principle (PP), although commonly thought of as rivals actually can be reconciled* "[635].

The underlying idea is to assign greater weights to human health and food safety concerns within a cost-benefit framework, through a modified cost-benefit analysis

[631]ALABRESE M., *TTIP e agroalimentare. Prime riflessioni a margine delle proposte dell'Unione Europea nella negoziazione della "Trans-Atlantic trade and investment partnership* in *Rivista di diritto agrario*, 2016, fasc. 2, pt. 1, p. 240

[632] With regard to the attention payed to the origin of products, see BORGHI P., *Passport please! WTO, Trips and the (serious?) question of geographical origin of foodstaff*, in *Studi in onore di Luigi Costato*, vol II, 2014, p.80

[633] BELLONI M. P. *Nel limbo degli OGM: Tra divergenze interpretative e disciplinari, alla ricerca di un accordo fra Stati Uniti e unione Europea, è questione di ethichetta, ma anche di etica*, in *Rivista di diritto pubblico comunitario*, 2006, p. 30 ss.

[634]This regulation has been adopted in 2011 under Obama administration and it marks a step forward for the American food security. See FERRARI M., IZZO U., *Diritto alimentare comparato*, Il Mulino, Bologna, 2012, p. 167-184. For a critical review of the American food law, see FORTIN N., *The US food safety Modernization Act: implications in transnational Governance of Food safety, Food system sustainability, and the tension with free trade*, in *Duke Environmental Law & Policy Forum*, Vol. 25, 2015, p.320 ss.

[635] COLE D. H., *Reconciling Cost-Benefit Analysis with the Precautionary Principle*, in *The Regulatory Review*, 5 March 2012, available at https://www.theregreview.org

which incorporates precautionary factors.[636] In fact, according to Schroeder, the catchy distinction between the EU precaution and the American aftercare, is questionable[637]. He argues that few decades ago, even if unlike EU Treaties, no constitutional basis for the precautionary principle exists, its legal nature has been recognized by the American Courts.[638] Moreover, even regarding the BSE crisis, one should not forget that the US reacted not only earlier but also more consistently than the EU Commission[639].

Therefore, "*the EU should find it difficult to insist, anyway, on the superiority of its regulations, since under the guise of differences in level of protection many factual cultural and subjective factors exist*"[640]. The same can be said about the alleged supremacy of the cost-benefit principle, which is not immune to criticisms. The quantification in terms of economic costs or gains, of "*highly unqualifiable factors*" like human health, food security and consumer protection, is the main one.[641] These values are too hard to be quantified and since cost-benefit analysis favors risk-toleration, such regulatory methodology is likely to create a situation where, as Geistfeld says, "*money matters more than safety*".[642]

Therefore, in the TTIP framework, the adoption of a modified cost-benefit analysis in the food sector, may represent the best solution to overcome the divergent regulatory principles between EU and US. On the one hand, when tolerable risks are at stake, the

---

[636]GEISTFELD M., *Reconciling Cost-Benefit Analysis with the Principle that Safety Matters More than Money*, in *N.Y.U. Law Review*, 2001, Vol. 76, n. 1, p.183

[637] SCHROEDER W., *Transatlantic Free Trade agreements and European Food standards*, in *European food and feed Law Review*, 2016, p. 497. The aftercare principle, as explain in Chapter 2, par.1 means "that it is only possible to ask the competent authority to establish a real health risk after the product has entered the market, and then impose a sales ban"

[638]WIENER B. J., *Better Regulation in Europe*, in *Current Legal Problems*, 2006, p. 447; In 1959 the Food Additives Amendment to the Food, Drugs, and Cosmetic Act of 1938 was adopted. The so-called "Delaney clause was a provision in the amendment thereby if a substance were found to cause cancer in man or animal, then it could not be used as a food additive. According to the American Court it should be interpreted as a "rigid provision", providing for a zero-tolerance policy.

[639]WIENER B., J., DOGERS M. D., *Comparing Precaution in the United States and Europe*, in *Journal of Risk Research,* 2002, p.317

[640]BERGKAMP L., KOGAN L., *Trade, the Precautionary Principle and Post-Modern Regulatory Process*, in *European Journal Risk Regulation*, 2013, p.507

[641]REVESZ R, *Environmental Regulation, Cost-Benefit Analysis, and the Discounting of Human Lives*, in *Columbia Law Review*, 1999, p.941

[642] See note 636

traditional calculation of costs and benefits may be relied upon, on the other, when unknown or especially dangerous risks exist, a risk-aversion approach that approximates the functioning of the precautionary principle may allow regulators "*to use economically preferred cost-benefit principle while also valuing safety at a higher level*"[643]. Whenever mutual recognition of standards cannot be achieved this new kind of regulatory methodology may be the key.

Therefore, when it comes to food safety standards, Parties should learn from each other's policy-making, seeking to set rules that incorporate an "adequate degree of precaution" but based on factors which can be "reliably assessed"[644]. On the part of EU, in fact, it is true that "*the precautionary principle is enshrined in the Lisbon Treaty and nothing in the TTIP could possibly change that*"[645], but only as far as efforts are undertaken to accept that sometimes the precautionary principle leads to more regulation than protection, regulatory reconciliation may be achieved.[646] At the same time, TTIP negotiations conducted so far, show that it is unlikely for US to accept the European approach to food law and it is mainly for what concerns sensitive issues like hormone-treated beef, that this happens.[647]

Owing to these difficulties, after 15 rounds of negotiations from 2013 to 2016, both the EU and US representatives recognized that even though "*negotiations are advanced*,

---

[643]FUNG S., *Negotiating Regulatory Coherence: The Costs and Consequences of Disparate Regulatory Principles in the Transatlantic Trade and Investment Partnership Agreement Between the United States and the European Union*, in *Cornell International Law Journal*, 2014, p. 471

[644]LOFSTETD R.E., *The Precautionary principle: Risks, Regulation and Politics, in Process Safety and Environmental Protection*, Volume 81, Issue 1, 2003, p. 36

[645] Karel De Gucht, European Trade Commissioner**,** *Transatlantic Trade and Investment Partnership (TTIP) – Solving the Regulatory Puzzle,* 10 October 2013

[646]BERGKAMP L., *The European Union REACH Regulation for chemicals: Law and Practice*, Oxford, 2013, p.414

[647] BONORA G., *Sul difficile nodo della carne trattata con ormoni nel "Transatlantic trade and investment partnership (TTIP)*, in *Rivista di diritto agrario*, 2016, fasc. 1, pt. 1, p. 137 According to the author three are the main reasons underlying this situation. First, the EU ban has always been felt as protectionism; secondly, it seems that American consumers do not care about the EU mistrust on the use of growth-hormones; third the American agri-business lobbying on the Government is directed in the opposite direction. Of the same opinion, see also APPLEGATE J. S., *The Precautionary Preference: An American Perspective on the Precautionary Principle, in Human and Ecological Risk Assessment: An International Journal*, 2000, Volume 6, Issue 3, p. 413

more work needs to be done"[648]. Anyway, TTIP could have represented a value-driven tool, leading to convergence of rules, but mainly to the emersion of common goals, from the environment to food safety.[649] **"***If the EU and US are up this challenge, in fact, both trade and risk regulation and ultimately the citizens of the world's two largest markets, will be the winners*"[650].

Yet, until now and from the food law prospective, TTIP represents only a missed opportunity to reconcile the EU precautionary principle and the American cost-benefit analysis in the food sector and we have to wait the ratification of CETA to really understand the goals which can be reached thereby FTAs.

3.2 The impact of CETA on EU food standards: the role of agri-business lobbying in the regulatory cooperation framework

"*While an agreement with Canada may seem less dangerous than an agreement with the United States, many of the American practices are prevalent in Canada and are just as concerning*".[651] As already said in Chapter 2, in the context of CETA, cooperation with regard to regulatory issues affecting European food standards, has been at the core of the public debate. Regulatory cooperation is included in multiple parts of CETA: in the Regulatory Cooperation Chapter as well as in the SPS and TBT Chapters[652]. The fear that through this mechanism food safety standards will be shaped on the less stringent Canadian model has been expressed all over Europe.

---

[648] Statement made during a stakeholders-meeting on 13 July, during the 14th Round of negotiations, 13-15 July 2016. The last Round was held in New York, from 3 to 7 October 2016

[649] See note 631, p. 242

[650] BERGKAMP L., KOGAN L., *Trade, the Precautionary Principle and Post-Modern Regulatory Process*, in *European Journal Risk Regulation*, 2013, p. 507

[651] *Europe: CETA puts your food safety at risk*, July 2016, available at https://canadians.org

[652] Respectively Chapter 21, Chapter 5, Chapter 4, also Chapter 25 on "Bilateral dialogues and cooperation" is relevant. Full text of CETA, explained chapter by chapter is available at http://ec.europa.eu/trade/policy/in-focus/ceta/ceta-chapter-by-chapter/

Yet, the question to be answered is whether this fear is substantiated.[653] Schroeder, Professor of European and International Law at the University of Innsbruck, argues that this agreement, as well as the TTIP, is not likely to endanger the strict EU food standards, for two main reasons. First, because even if it is true that "Parties are committed to further develop regulatory cooperation in light of their mutual interest", this may only happen "*without limiting the ability of each Party to carry out its regulatory, legislative and policy activities*"[654].

This provision means that none of the measures agreed by Canada and EU have a binding nature and that cooperation only works "on a voluntary basis"[655]. Moreover, even the Regulatory Cooperation Forum (RCF), established to promote regulatory cooperation, represents only a forum to discuss and to review regulatory initiatives[656] and it is not entitled to make binding decisions on the recognition of standards.

Yet, albeit from a formal point of view the level of commitment of the parties appears very low, the situation is not as easy as it seems. The NAFTA experience, in fact, "*shows that even voluntary regulatory cooperation may lower standards, reduce transparency and increase corporate influence on the regulatory process*"[657]. The

---

[653] SCHROEDER W., *Transatlantic Free Trade Agreements and European Food Standards,* in *European Food and Feed Law Review (EFFL)*, Vol. 2016, Issue 6, 2016, p. 501

[654] See Article 21.2. 4 CETA. The aims of regulatory cooperation are to: (a) prevent and eliminate unnecessary barriers to trade and investment;(b) enhance the climate for competitiveness and innovation, including by pursuing regulatory compatibility, recognition of equivalence, and convergence; and (c) promote transparent, efficient and effective regulatory processes that support public policy

[655]Chapter 21, Article 21.2.6

[656] Chapter 21, Article 21.6.2 "The RCF shall perform the following functions: (a) provide a forum to discuss regulatory policy issues of mutual interest that the Parties have identified through, among others, consultations conducted in accordance with Article 21.8; (b) assist individual regulators to identify potential partners for cooperation activities and provide them with appropriate tools for that purpose, such as model confidentiality agreements; (c) review regulatory initiatives, whether in progress or anticipated, that a Party considers may provide potential for cooperation. The reviews, which will be carried out in consultation with regulatory departments and agencies, should support the implementation of this Chapter; and (d) encourage the development of bilateral cooperation activities in accordance with Article 21.4"

[657]TREAT S., *CETA, Regulatory Cooperation and Food Safety, in IATP, Greenpeace and Canadian Centre for Policy Alternatives (CCPA*), September 2015, p. 5, avaiable at https://www.iatp.org/documents/ceta-regulatory-cooperation-and-food-safety She argues that the US-Canada Regulatory Cooperation Council (RCC) uses to rely heavily on industry guidance and participation, its website contains only limited information. According to Sharon Treat, red flags should

experience of the Regulatory Cooperation Council (RCC) between Canada and US, offers the evidence of how regulatory cooperation may serve as an open door for business lobbying, ready to challenge precautionary measures hindering international trade of food products.[658]

According to Trew, member of the Canadian Center for Policy Alternatives, in several provision of CETA's Chapter 21 (Regulatory Cooperation), the footprint of corporate lobbying is not difficult to be identified. First, whenever Parties propose sanitary of phytosanitary measures which may affect trade of food products, they shall share the relevant information with the other Party "at the earliest stage possible so that comments and proposals for amendments may be taken into account"[659]. Second, "other interested parties"[660] are invited to participate in the meetings of the RCF. Third, the contact points for communication between Canada and EU on matters arising under this Chapter are respectively the Technical Barriers and Regulations Division of the Department of Foreign Affairs, Trade and Development, and the International Affairs Unit of the Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs.[661] It is clear that their mandate is to enhance trade and not to protect consumer or ensure food safety and therefore "*all these provision suggest whose interests will be most served by cooperation*"[662].

Since the corporations' objective is to maximize profits, it is now more evident why critics suggest that the involvement of agri-business in CETA's negotiations first and

be raised about the CETA RCF, since it appears to be modelled on the NAFTA Regulatory Cooperation Council, which is actually a bad model

[658]TREW S., *From NAFTA TO CETA: Corporate lobbying through the back door*, Canadian Centre for Policy Alternatives, Corporate Europe Observatory, Forum Umwelt und Entwicklung and LobbyControl, 9 February 2017, p. 4

[659] Chapter 21, Article 21.4.d

[660] Chapter 21, Article 21.6.3 "The RCF shall be co-chaired by a senior representative of the Government of Canada at the
level of a Deputy Minister, equivalent or designate, and a senior representative of the European Commission at the level of a Director General, equivalent or designate, and shall comprise relevant officials of each Party. The Parties may by mutual consent invite other interested parties to participate in the meetings of the RCF."

[661] Chapter 21, Article 21.9.1

[662] See note 658, p. 17

in the decision-making process then, will result in lower food safety standards.[663] Moreover, "*not all businesses are expected to gain from the agreement*"[664]. In fact, albeit consultations with private entities are specifically addressed "in order to gain non-governmental perspectives"[665] too, only those private actors with the closest connection to the trade officials and the biggest budget in terms of economic resources, will find the door open. In Italy, for instance, where the market is dominated by small and medium sized enterprises (SMEs), "*the general fear is that these companies will be crushed by giants*"[666].

A clear example of the pressure that transnational giants are able to exercise, is represented by the experience of two global companies[667], leaders of the meat market in Canada, US, Brazil and Mexico, which have spent time and resources lobbying the Canadian and US governments in order to obtain the removal of the Country of Origin Labelling (COOL)[668]. The global meat industry, in fact, considers COOL "as a barrier to expanding meat sales"[669].

---

[663] VON ENDT M., *Is TAFTA/TTP a Race to the Bottom in Regulatory Standards?: The Case of Hormone Treated Beef* in *The Transatlantic colossus: global contributions to broaden the debate on the EU-US free trade agreement*, Daniel Cardoso et al. eds., 2013, p. 101

[664] To analyze the same considerations in the TTIP framework see WATTS J., *The Transatlantic Trade and Investment Partnership: An Overly Ambitious Attempt to Harmonize Divergent Philosophies on Acceptable Risks in Food Production without Directly Addressing Areas of Disagreement* in *North Carolina Journal of International Law*, Vol. 41, Issue 1, 2015, p. 127

[665]Chapter 21, Article 21.8

[666] VON DER BURCHARD H., BARIGAZZI J., *Europe's Trade Fears: chlorine chicken, secret courts*, in *POLITICO*, July 2015, available at https://www.politico.eu

[667]JBS and Cargill. JBS in particular, is the largest meat processor in the world. In 2017 owing to a food safety scandal concerning tainted meat exports, it was at the center of public debate; see FREITAS G., FREITAS T., *Brazil meat giants rush to contain scandal*, 20 March 2017, available at https://www.bloomberg.com. In response the EU and other countries banned meat imports, but then decided to remove them; see PARAGUASSU L., PATTON D., *China, others lift ban on meat imports in boost for Brazil*, 25 March 2017, available at *https://www.reuters.com*

[668] This type of labelling laws allows consumers to know where their foods come from, a demand which is getting more and more important owing to the phenomenon of the global value chain, described in Chapter 1, par. 3

[669]For a general overview on the issue see THOMSEN B., *CETA's threat to agricultural markets and food quality*, in MERTINS-KIRKWOOD (ed.) *Making Sense of CETA: An analysis of the final text of the Canada-European Union Comprehensive Economic and Trade Agreement*, Berlin and Ottawa: PowerShift and CCPA, 2016.

Therefore, on behalf of these two giants, Canada started a dispute before the WTO Dispute Settlement Body to force US to remove a national measure, requiring corporations to indicate all countries where the animal respectively has been born, raised and slaughtered.[670] In 2015, the WTO ruled in favor of Canada, finding that the American COOL was unfair to Canadian meat producers[671]. After this ruling the US repealed the labelling scheme not only for beef and pork meat but also for poultry. This dispute has made clear that through the WTO "*meat industry has been able to achieve what it has been unable to accomplish after years and years of lobbying*"[672].

When it comes to EU rules on COOL[673], initially adopted after the BSE crisis, one should not forget that the EU Parliament as well as many Member States are moving forward with even more stringent rules, in order to expand the application of COOL rules not only to fresh meat but also to processed products.[674] Understood this intent, it is not difficult to acknowledge why CETA may represent a danger for EU COOL rules and more in general for EU food safety standards.[675]

In addition to the WTO dispute settlement system and the above-mentioned power to intervene at the early stages of regulatory cooperation, in fact, CETA will grant to

---

[670]United States - Certain Country of Origin Labelling (COOL) Requirements - Recourse to article 21.5 of the DSU by Canada and Mexico - AB-2014-10 - Reports of the Appellate Body, WT/DS384/AB/RW; WT/DS386/AB/RW

[671] The Appellate Body upheld, albeit for modified reasons, the Panel's finding that the COOL measure was inconsistent with Art. 2.1 WTO TBT Agreement because it accorded less favourable treatment to imported livestock than to like domestic livestock

[672] SHARMA S. , IBRAHIM N., *How CETA Can Endanger Country of Origin Labelling,* in *IATP, Greenpeace and Canadian Centre for Policy Alternatives (CCPA),* p. 2, avaiable at *https://www.iatp.org/documents/how-ceta-can-endanger-country-origin-labelling-cool*

[673]Now Regulation (EU) No 1169/2011 on the provision of food information to consumers, providing for Mandatory origin information for fresh meat from pigs, sheep, goats and poultry. The first piece of EU secondary law adopted after the BSE crisis and still in force is Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97

[674] Member States such as Italy, Latvia, Portugal, Romania, Greece, Finland and Spain are working for including also rules of origin for non-animal products such as wheat.

[675]According to a BEUC consumer survey on origin labelling on food, "recent years have seen a growing interest on the part of European consumers to know the origin of the food they buy". Yet, the reasons behind consumers' interest in the origin of their food vary between countries: they are mainly food safety, food quality, environmental impact and ethical concerns. See BEUC, *Where does my food come from*?, 2013, p. 5-13

multinational corporations even another tool for challenging EU rules: the already mentioned Investor Court System[676] (ICS). Both Brazilian JBS and the US Cargrill, the transnational corporations which "together account for more than 90 per cent of Canada's inspected beef-packing industry" [677], have their seats in the European territory. The ICS would empower foreign investors to challenge COOL rules adopted by the EU as well as by Member States, as far as they undermine their profits or hade a discriminatory nature.[678]

Therefore, the problem is not, how Schroeder argues, "*that the CETA prevents laws and regulations outright. It is that the CETA will make some laws and regulations too risky to pursue by putting an uncertain and potentially huge price tag on them*."[679] A clear example of this contradictory situation is given by the EU-Canada Joint Interpretive Declaration on the CETA[680].

It states that "*The European Union and its Member States and Canada will continue to have the ability to achieve the legitimate public policy objectives such as public health, safety, environment... CETA will also not lower our respective standards and regulations related to food safety, product safety, consumer protection, health, environment. Imported goods, service suppliers and investors must continue to respect domestic requirements, including rules and regulations. The European Union and its*

[676]With regard to the Italian initiative to adopt a mandatory country-of-origin label (COOL) for pasta, Cam Dahl, president of Cereals Canada, said: "We can't assume that that is going to happen, so we do have to prepare, whether that's WTO action, or whether there are measures under the Canada-EU trade agreement. We have to prepare for that." see HEPPNER K., *COOL Looms Again, This Time on Durum Exports to Italy*, 11 April 2017, available at https://www.realagriculture.com

[677]Submission of the National Farmers Union to the House of Commons Standing Committee on Agriculture and Agri-food regarding *Agricultural Impacts of the Canada-European Union Comprehensive Economic and Trade Agreement*, 5 December 2014, p. 3 According to it, Canada's beef and pork processing sectors are highly concentrated in the hands of these two foreign-owned companies, Cargill (USA) and JBS (Brazil).

[678] See note 669, p. 5

[679] VAN HARTEN G., *The EU-Canada Joint Interpretive Declaration/Instrument on the CETA*, Osgoode Legal Studies Research Paper No. 6/2017, Volume 13, Issue 2, 2017, p. 4

[680] *Joint Interpretative Instrument on the Comprehensive Economic and Trade Agreement* (CETA) between Canada and the European Union and its Member States, Brussels, 27 October 2016, 13541/16

Member States and Canada reaffirm the commitments with respect to precaution that they have undertaken in international agreements"[681].

According to Van Harten, these statements circumvent the key problem, meaning that CETA tribunals will have the power to order the state concerned "to pay uncapped amounts of compensation to foreign investors"[682]. Moreover, one should not forget that, in light of the ECJ Opinion 2/15, Belgium has requested an advisory opinion to the Court concerning the compatibility of the Investment Court System (ICS) with the autonomy of the EU legal order.[683]

In conclusion, on the one hand the claim that regulatory cooperation may lead to binding measures lowering EU food standards or replacing the precautionary principle is mostly unsubstantiated[684]. On the other, the possibility that Member States may be prevented from adopting protective measures for food safety and consumers by the risk to face costly claims by agribusiness, is on the contrary, a real threat.[685]

---

[681] Ibid, p. 3

[682] See note 679, p. 2 Moreover, for Member States the risk to be sued would be even more likely if it is a large multinational or a billionaire who can afford high legal fees

[683]CETA: Belgian request for an opinion from the European Court of Justice, 27 October 2016, avaiable at https://diplomatie.belgium.be/sites/default/files/downloads/ceta_summary.pdf For a detailed analysis on the criticalities related to the ICS and the interpretative monopoly of the ECJ, see GALLO D., *Scope, extent and limits of the new system of the investment disputes resolution in the recent free trade agreements of the European Union* in *Il Diritto del commercio internazionale*, 2016, fasc. 4, p. 852-861. The CETA's provisions, subject of the Belgian opinion request to the CJEU, are excluded from the provisional implementation of the Treaty. For an overview of the latest development on CETA see HARTE R., European Parliamentary Research Service *CETA ratification process: Latest developments*, October 2017, p. 1-3

[684]COUVREUR A., *New Generation Regional Trade Agreements and the Precautionary Principle: Focus on the Comprehensive Economic and Trade Agreement (CETA) between Canada and the European Union* in, *Asper Review of International Business and Trade Law*, Vol. 15, p. 284. According to the author, without strong commitments being at stake, the CETA regulatory framework "does not prevent either of the Parties from conserving their respective approaches to risk regulation"

[685]See, inter alia, BARONINI D., *Il trattato Ceta sposta la sovranità dai popoli alle multinazionali*, September 2017, avaiable at http://contropiano.org; KOETH W., European Institute of Public Administration, *Can the Investment Court System (ICS) save TTIP and CETA?*, in *EIPA Working Papers*, 2016, p. 9 "Even if one could imagine the effect of 'regulatory chill' on some regulators, it could be argued that one of the effects of ISDS could be a 'protectionist chill', making regulators think twice about introducing new barriers to trade that would be justified not by public interest but as protectionist barriers"

Therefore, since national Parliaments still have the right to cancel this deal, by refusing to ratify it, they cannot avoid facing all these critical issues in order to choose what's the right thing to do.[686]

3.3 The limits of the WTO's multilateral trading system and the role of Free Trade Agreements in safeguarding food safety standards

In recent years, "*food-borne hazards and illnesses have become a serious problem of international concern*"[687]. In the framework of the current economic globalization, where states' borders have become more and more permeable to the flow of goods and food products, also food-safety problems are now "globalized".[688] The key factors of this situation are different: the increasing development of food science, new transportation technologies and the unstoppable economic and physical growth of transnational food enterprises in the food industry.[689]

Yet, even if a global solution is needed, addressing global food-safety issues, does not necessarily imply a multilateral legal regime.[690] As Chapter 1 par. 3 has shown in fact, the dysfunction of the WTO system has led to a shift towards bilateral agreements, which more and more shape the food sector through the so called "SPS-plus" provisions, seeking to go beyond the commitments included in the WTO SPS

---

[686]TREAT S. *CETA, Regulatory Cooperation and Food Safety, in IATP, Greenpeace and Canadian Centre for Policy Alternatives (CCPA),* 20 September 2017, p.11, available at https://www.iatp.org/documents/ceta-regulatory-cooperation-and-food-safety

[687]See generally GANGAHAR P., *Food Safety and Management System*, in SINGH S.P. *Food safety, quality assurance and global trade: concerns and strategies*, 2009, p.25 ss.

[688] World Health Organization [WHO], WHO Global strategy for food safety: safer food for better health, Geneva, 2002, p. 5-6

[689]World Economic Forum, *The Global Risks Report* 2017, 12th Edition, p.16-17

[690]LIN C., *SPS-Plus and Bilateral Treaty Network: A Global Solution to the Global Food-Safety Problem?* in *Wisconsin International Law Journal*, Vol. 29, Issue 4 (Winter 2012), p. 697 The term multilateral includes not only the WTO, but also the World Health Organization (WHO), and the Codex Alimentarius. The WHO, as some scholars argue, "has failed to provide leadership or facilitate better governance in the area" See TAYLOR A. L., *Making the World Health Organization Work: A Legal Framework for Universal Access to the Conditions for Health*, in *American Journal of Law and Medicine*, 1992, p. 301;

Agreement.[691] Moreover, also the quite recent phenomenon of the "global value chain"[692], has two further consequences on the global food law. On the one hand, by requiring the involvement of producers, distributors and consumers from different States, criticalities concerning the application of different safety and quality standards come to the fore.[693] On the other, the increasing risk of contamination of food products from the farm to the table has strengthened consumers' attention about food safety and traceability.[694]

Therefore, since this interconnection leads to the need of regulatory cooperation to reduce costs and increase consumer protection, it seems that both these issues may be correctly addressed by the new generation of free trade agreements which, as underlined in Chapter 2, are intended to create "deep integration" partnerships.[695]

Yet, as Schroeder underlines, this term shall not be misunderstood, since while these agreements are "*supposed to go beyond what has been achieved so far within the WTO framework, conditions analogous to those of the EU internal market are not envisioned too*"[696]. At least in theory, in fact, the idea that FTAs may produce positive impacts on the international food market, shows its advantages compared to the multilateral or unilateral approaches.[697] First, bilateral relationships ensure Parties more flexibility and discretion in the choice of their partner and of the content of negotiations. Second, the

[691]For a general overview on the issue see ALABRESE M., *Gli accordi commerciali mega-regionali e l'elaborazione del diritto agroalimentare* in *Rivista di diritto agrario,* fasc. 1, 2017, pt.1, p. 136-152; The author defines "SPS-plus" as "legal instruments that are signed by countries and that include more detailed or demanding provisions than the multilateral rules under the SPS Agreement, or that contain other regulatory or cooperative elements beyond the scope of the SPS Agreement"

[692]The chain is due to the fact that a food product may be made in one place with materials coming from several countries and then entering into the supply chain, moving to far locations to be processed and then consumed in many regions.

[693] See note 691, p. 144

[694] DELOITTE, *The food value chain A challenge for the next century*, 2013, p. 3

[695] World Trade Report 2011, The WTO and preferential trade agreements: from coexistence to coherence, p.111, available at www.wto.org

[696] SCHROEDER W., *Transatlantic Free Trade agreements and European Food standards*, in *European food and feed Law Review*, 2016, p. 501

[697]XING L., *Surprise under the table: Inspirations from the Canada-EU CETA for Enhancing Global Agri-Environment by FTAs*, in *Asper Review of International Business and Trade Law*, Vol. 13, 2013, p. 238

bilateral setting is more susceptible to be exploited even in terms of enforcement.[698] Third, the more is the economic gain at stake, the more each Party may consent to be influenced by the protective standards of the other Party.[699]

Divergent regulatory trade barriers, in fact, are the key issue in these Agreements. Chapter 2 has shown how these divergences can arise for several reasons; parties may seek to achieve different goals or, even if the goal is the same, national laws may adopt certain measures without taking into consideration what foreign counterparts are doing.[700]

Yet, one should not forget the limits of regulatory cooperation meaning that it shall nor turning into more regulation, neither into a less protective one.[701] Therefore, to reach this balance, for global food-trade players like the US, EU, Canada and China, bilateralism offers an approach which is more flexible and pragmatic than the multilateral one.[702]

The WTO, in fact, has always labelled food safety only as a trade issue, without playing an active role for improving global food safety.[703] Even the SPS Agreement, described in Chapter 1 par.3, is not aimed at ensuring global food safety, since it represents only a tool regulating a particular kind of exceptions for the purpose of trade

[698]In this sense see BLUM G., *Bilateralism, Multilateralism, and the Architecture of International Law*, in *Harvard International Law Review*, 2008, p.356-357

[699] Ibid. The author underlines that "the multilateral approach does not provide individual countries with sufficient consensus or confidence to lead multilateral negotiations on pertinent issues" and that "unilateral measures integrate agri-environmental benchmarks into domestic agricultural legislation without increasing market access for imports from a third country"

[700] LESTER S., BARBEE I.., *The Challenge of Cooperation: Regulatory Trade Barriers in the Transatlantic Trade and Investment Partnership* in *Journal of International Economic Law*, Volume 16, Issue 4, 1 December 2013, p. 853

[701] BONORA G., *Sul difficile nodo della carne trattata con ormoni nel "Transatlantic trade and investment partnership (TTIP)*, in *Rivista di diritto agrario*, 2016, fasc. 1, pt. 1, p. 136. The author argues that with regard to food safety standards in the framework of globalization and free-market, two opposites views shall be taken into account: On one hand, there are those claiming that the more free-trade is pursued, the more a "race to the bottom" for food standards and health protection is undertaken. On the other, some scholars maintain that, as far as certain conditions are fulfilled, these kinds of standards can be "raced to the top".

[702]See note 698, p. 339

[703]LIN C., *Global Food Safety: Exploring Key Elements for an International Regulatory Strategy*, in *Virginia Journal of International Law*, Vol. 51, Issue 3, 2011, p. 665

liberalization.[704] Therefore, the reason for incorporating an SPS chapter into FTAs, lies in the fact that the WTO rules on food safety have not produced the expected effects in terms of positive harmonization of food standards.[705]

Definitely, it is undeniable that the Doha WTO Ministerial Declaration adopted in 2001, has emphasized the Parties' commitment to include, in future negotiations, the promotion of non-trade issues such as food safety. The underlying common idea, in fact, is that "*under WTO rules no country should be prevented from taking measures for the protection of human, animal or plant life or health, or of the environment at the levels it considers appropriate*"[706].

Yet, many scholars identify several obstacles to the development and implementation of this prospective.[707] First, since the Doha Round is currently stalemate and its future remain uncertain, a multilateral solution to global food safety issues is not likely in the short term. Second, in the resolution of food safety related cases (see the EC-Hormones and the EC-Biotech disputes, discussed in chapter 2.1.2), the decisions of the WTO Dispute settlement body (DSB) have often shown their own limits.[708] On the one hand, the DSB albeit paying attention to the protection of human health, has used to interpret WTO rules in a narrow way without going beyond what is set out in their texts.[709] On

[704] SILVERGLADE B.A., *The WTO Agreement on Sanitary and Phytosanitary Measures: Weakening Food Safety Regulations to Facilitate Trade?, in Food & Drug Law Journal*, 2000, p. 517-20

[705] ORDEN D., JOSLING T., *Sanitary and Phytosanitary barriers to agricultural trade: progress, prospects, and implications for developing countries*, in *Agriculture and the New Trade Agenda. Creating a global trading environment for development*, New York, Cambridge University Press, 2004, p.330

[706] DOHA WTO Ministerial 2001: Ministerial declaration, adopted on 14 November 2001, WT/MIN(01)/DEC/1, p.6

[707]See, inter alia, LUPONE A., *Balancing basic human needs and free trade in the WTO*, in LUPONE A., RICCI C., SANTINI A. (eds.) *The right to safe food towards a global governance*, Torino, Giappichelli, 2013, p.103-112; ALABRESE M., *Gli accordi commerciali mega-regionali e l'elaborazione del diritto agroalimentare* in *Rivista di diritto agrario*, fasc. 1, 2017, pt.1, p. 136-152; PETROVETS K. A., *Moving towards harmonization of food safety standards: Role of the TTIP and TTIP Agreements*, in *Journal of Food Law and Policy*, 2016, p. 112-139

[708]PETROVETS K. A., *Moving towards harmonization of food safety standards: Role of the TTIP and TTIP Agreements*, in *Journal of Food Law and Policy*, 2016, p. 133

[709]For instance, in the EC-Hormones case the Appellate Body claimed that the precautionary principle "has not been written into the SPS Agreement as a ground for justifying SPS measures that are otherwise inconsistent with the obligations of members set out in particular provisions of that agreement", see

the other hand, the more the case concerned is closely connected to public health and food safety policies, the less it is likely that the respondent State will comply with the DSB decisions and change its whole legal system.[710]

Moreover, at the international level, "*a comprehensive, multilateral agreement that addresses food safety issues on a single legal and political platform does not seem to be on the agenda of either the WTO, the WHO, or the Codex Alimentarius and consequently this situation discourages States from seeking multilateral solutions for the present*"[711].

Therefore, as Blum emphasizes, to make food-safety governance working properly, "*the supposed benefits of multilateral treaties are often not as great as advertised or expected, and the effects of bilateral treaties are not necessarily as limited as universalists fear or unilateralists hope*"[712]. At the same time, one should not forget that the more bilateral agreements addressing regulatory cooperation in the food sector are concluded, the more it is the risk that a situation of confusion and contradiction may come to the fore.[713] As the 2013 Director-General of the WTO underlined, in fact, "*while bilateral tariff reductions can ultimately be multilateralized, a plethora of bilateral trade agreements will produce a multitude of regulatory standards with which business will struggle to comply*"[714].

WT/DS26/AB/R, *European Communities -Measures concerning meat and meat products*, Report of the Appellate Body, 16 January 1998, par.124

[710]For instance, albeit the WTO DSB has considered many times the precautionary principle as an unscientific tool, the EU keeps on using it in all its decision-making policies. Another example of the lack of effectiveness of the WTO decisions is the EC-Hormones case. Despite the Appellate Body (AB) decision in favor of USA and Canada, the EU continued with the enforcement of the prohibitive regulations on the use of growth-hormones, until the MOU signed in 2009

[711]LIN C., *SPS-Plus and Bilateral Treaty Network: A Global Solution to the Global Food-Safety Problem?* in *Wisconsin International Law Journal*, Vol. 29, Issue 4, 2012, p. 703

[712]See 698, p. 325

[713] LESTER S., BARBEE I.., *The Challenge of Cooperation: Regulatory Trade Barriers in the Transatlantic Trade and Investment Partnership* in *Journal of International Economic Law*, Volume 16, Issue 4, 1 December 2013, p. 866

[714]LAMY P., *Putting geopolitics back at the trade table*, speech at the IISS-Oberoi Discussion Forum in Delhi on 29 January 2013, available at https://www.wto.org/english/news_e/sppl_e/sppl264_e.htm

Anyway, despite this assumption and considering the above mentioned limits of the WTO's multilateral dimension, a network of bilateral agreements incorporating multiple SPS-plus commitments is considered the best solution for improving global food safety.[715] Nowadays, in fact, the new generation of FTAs appears to be the best forum where negotiating Parties can learn from each other, because even countries like the EU Member States, with rigid food laws, "*cannot avoid suffering from the insufficiency and the ineffectiveness of one another's food-safety regulations*"[716].

Moreover, since binding rules concerning risk regulation and regulatory cooperation are set nor under CETA, neither under the TTIP, the voluntary approach to cooperation and the inclusion of the so-called "Good regulatory practices", can represent a step forward for bridging divergent approach to food safety and to intensify the transatlantic dialogue [717]. As Pollack emphasizes, in fact, "*institutionalized forms of political cooperation and periodical consultation with a constant exchange of information and views on sensitive transatlantic regulatory disputes are often considered more appropriate than binding bilateral agreements or WTO litigation*"[718].

Even a "domino effect" in the global arena has been attributed to these FTAs. Since the EU food safety standards ensure a high level of consumer and human health protection, all EU's FTA partners with a weaker public-health system, are expected to strengthen their food safety governance from this partnership. At the same time, FTAs concluded by US, Canada, Vietnam, Singapore and others, can generate positive externalities for other parts of the world, thus creating a diffusion effect of standards.[719]

---

[715] See note 711, p. 731

[716]See GOSTIN O. L., *Public Health Law in a New Century: Part I: Law as a Tool to Advance the Community's Health*, in 283 *JAMA*, 2000,

[717]COUVREUR A., *New Generation Regional Trade Agreements and the Precautionary Principle: Focus on the Comprehensive Economic and Trade Agreement (CETA) between Canada and the European Union* in, *Asper Review of International Business and Trade Law*, Vol. 15, 2015, p. 286

[718]POLLACK A., *The political economy of transatlantic trade disputes*, in PETRSMANN E. U., POLLACK A. (eds.) *Transatlantic Economic Disputes*, 2003, p.73

See also GERDEGEN M., *Legal challenges for transatlantic economic integration*, in *Common Market Law Review*, Volume 45, Issue 6, 2008, p. 1581–1609

[719]XING L., *Surprise under the table: Inspirations from the Canada-EU CETA for Enhancing Global Agri-Environment by FTAs*, in *Asper Review of International Business and Trade Law*, Vol. 13, 2013, p. 237; in the same sense see also LIN C., *SPS-Plus and Bilateral Treaty Network: A Global Solution to*

Obviously, these cumulative effects will be broader as far as Parties are in a paramount driver position in global value chains and this is why TTIP has been defined as "*a game changer not only for our future bilateral trade and investment but also for the development of global rules*"[720].

At last, *"embraced the idea that the existence of diverse food-safety standards is the norm rather than the exception*"[721], the FTAs repercussions on the global governance of food standards deeply depends upon their characteristics and can only be assessed in the long term on the basis of several factors. Such an outcome, in fact, depends on the States' will to learn from each other[722], on the way how the relevant stakeholders are included in the institutional bilateral bodies addressing regulatory cooperation[723], on the reciprocal commitment to find a common ground in risk evaluation procedures[724] and in the bravery to address "*most of the innovative and truly debatable*

the Global Food-Safety Problem? in *Wisconsin International Law Journal*, Vol. 29, Issue 4 (Winter 2012), p. 731 "Positive externalities of bilateral food-safety agreements can multiply, and thus, may help construct and strengthen a regulatory net"

[720]DE GUCHT K., European Trade Commissioner, Transatlantic Trade and Investment Partnership: Opening Free Trade Negotiations with the United States, Speech Before the Committee on International Trade (INTA) of the European Parliament/Brussels, 21 February 2013, available at http://europa.eu/rapid/press-release_SPEECH-13-147_en.htm; see also OECD, '*The Transatlantic Trade and Investment Partnership: Why Does it Matter*?', 13 February 2013, thereby "Given that regulatory matters are expected to be at the heart of any eventual agreement, transparency in the way regulations are made and implemented will allow other countries, not party to the agreement, to consider whether and how to—opt-in. … Extending mutual recognition of standards to third countries, with which either the United States or European Union has already reached a comparable agreement, is another possible way of ensuring that the benefits of TTIP are extended more globally"

[721]World Bank, *Food Safety and Agricultural Health Standards: Challenges and Opportunities for Developing Country Exports*, Report No. 31207, 10 January 2005, p.32

[722] BERGKAMP L., KOGAN L., *Trade, the Precautionary Principle and Post-Modern Regulatory Process*, in *European Journal Risk Regulation*, 2013, p.504

[723] One of the proposed food law provision in the TTIP provided for the establishment of a special joint EU-US management committee, composed by trade and regulatory experts. CETA provides for the Regulatory Cooperation Forum (RCF) in Chapter 21

[724]PEEL J., *Science and Risk regulation in International Law*, New York, Cambridge University Press, 2010, p. 10; that author underlines that "emerging as a crucial issue for global risk regulation is not whether science or values should triumph, but rather how scientific and non-scientific inputs might be blended in risk assessment in different settings to ensure a broadly acceptable balance of credibility and legitimacy concerns

food safety issues, such as regulation of growth hormones, the use of biotechnology on food products and animal cloning"[725].

Since TTIP negotiations are stalled, the CETA ratification process is on-going and the EUSFTA and EUVFTA are still to be signed, success in this area will not be easily achieved. Yet, from the global governance of food safety, the related gains are potentially great and thus an attempt to solve the long-standing issue of regulatory cooperation is worth the effort.[726]

3.4 Comprehensive evaluation of the Regulation (EC) No 178/2002 and prospective strategic policies in the food sector: The limits of European food law and its role as a model for the global governance of food standards

Since the beginning, the aim of the present work has been to emphasize the impact that the complexity and the high-quality of the EU food law may have on the negotiations of the new generation free trade agreements and the other way around.

Chapter 1, par.2 has described the origin and development of such a complex system: back in the 1960s instruments of "positive integration" were adopted, in order to supplement the "negative integration" rules set forth in the Treaties.[727] The complexity of EU food law is also a consequence flowing from the fact that the food sector has a "transversal" nature and therefore, as far as food safety is concerned, the EU action

[725]PETROVETS K. A., *Moving towards harmonization of food safety standards: Role of the TTIP and TTIP Agreements*, in *Journal of Food Law and Policy*, 2016, p. 140

[726] LESTER S., BARBEE I., *The challenge of cooperation: Regulatory Trade Barriers in the Transatlantic Trade and Investment Partnership*, in *Journal of International Economic Law*, 2013, p. 867

[727]SANTINI A., *European food law ten years after Regulation (EC) No 178/2002*, in. LUPONE A., RICCI C., SANTINI A. (eds.) *The right to safe food towards a global governance*, Torino, Giappichelli, 2013, p.25; "Negative integration" rules are Articles 30, 34, 16 TFEU, which represent the leading principles for the establishment and functioning of the EU internal market. "Positive integration" rules were mainly vertical directives in the first phase and horizontal regulations after the adoption of the Regulation 178/2002 which rationalized the whole legislative framework.

relies upon multiple legal basis.[728] Moreover, the regulation of the free movement of food within the EU food market as well as between the EU and third countries has always been characterized by multiple objectives: ensuring free trade, while protecting human health and consumers.[729] This is why it has been said that, "*EU food law is an hybrid object in constant search of balance*"[730] and both the EU's WTO disputes, where European law is often in contrast with the international norms addressing food safety, and the public debate concerning CETA and TTIP clearly show how difficult is to find it.

In such balancing, consumer protection has always represented a crucial value for the EU, at least since the 1990s, when the complete opening of the internal market through the *Cassis* case and the public concern raised by food scandals, led EU institutions to acknowledge the urgent need to grant food quality and food safety in a more proactive way.[731]

Yet, as the comparative examination with third countries' food law has shown, the EU use of the precautionary principle and of the so-called 'farm-to-fork' approach[732] to food safety, as opposed to the 'end-of-pipeline' approach, has made EU food law an

[728]See par 1.2.3 concerning the provisions included by the Amsterdam Treaty. Moreover, the preamble of the Regulation 178/2002 includes four provisions as the legal basis for the regulation itself: Article 43 TFEU (on the implementation of the common agricultural policy; Article 114 TFEU (on the approximation of laws), Article 168, par.4 (on the adoption of sanitary and veterinary measures); Article 207 TFEU (on the common commercial policy). Moreover, on the relation between EU food safety and the principle of conferral see ZILLER J., SALA-CHIRI G., *The EU multilevel food safety system in the context of the principle of conferral*, in LUPONE A., RICCI C., SANTINI A. (eds.) *The right to safe food towards a global governance*, Torino, Giappichelli, 2013, p. 229-237

[729] COSTATO L., BORGHI P., RIZZIOLI S., *Compendio di diritto alimentare*, 2011, Padova, p. 156; see also VAN DER MUELEN B., VAN DER VELDE M., *European Food Law Handbook*, 2009, Wageningen, p. 253

[730]AZOULAY L., *La securitè alimentaire dans la lègislation communautaire*, in BOURRINET J., SNYDER F. (eds.) *La securitè alimentaire dans l'Union europèenne*, 2003, Bruxelles, p. 31

[731] GENCARELLI F., *Ultimi sviluppi della politica UE di qualità alimentare: "Pacchetto qualità" e origine dei prodotti*, in RICCI C., LUPONE A., SANTINI A., *La tutela multilivello del diritto alla sicurezza e qualità degli alimenti*, Giuffrè, p. 319

[732] This approach entails measures ensuring a high level of food safety for food products at all stages of the production and distribution chains of food products. It applies both to products produced within the European Union and to those imported from third countries.

over-regulated framework.[733] Even the European Parliament in a resolution adopted in 2009, albeit underlying that "*the European Union has the highest quality and standards for food products in the world*", was "*concerned at the complexity of the EU system of basic standards and at the multiplicity of rules which farmers and producers in the European Union have to comply with"* and therefore, called for "*a simplified system to be assessed in accordance with the criteria of suitability, necessity and proportionality*"[734].

Therefore, since the need to reduce regulatory costs, repeal unnecessary legislation and administrative burdens has represented one of the main priorities included in the EU Commission's agenda, the EU food safety legislative framework is currently being reviewed.[735]

Chapter 2, in fact, has shown how even current and future bilateral trade negotiations "*are exposing EU producers to direct international competition, and that any additional measures that have to be complied with, may be detrimental in this regard*"[736]. It means that the examined FTAs may represent not only a challenge, but even an opportunity for the European food safety approach, since they may let EU institutions acknowledge that more regulation does not always mean better regulation.[737]

This is particularly true in the field of biotechnology and "novel foods", where the rapid technological developments are meant to generate "the next industrial revolution".[738]

---

[733]European Parliament, DG for internal policies, Food safety: state-of-play, Current and Future challenges, Policy Department A: Economic and Scientific Policy, October 2014, p. 10

[734] European Parliament resolution of 10 March 2009 on ensuring food quality, including harmonization or mutual recognition of standards (2008/2220(INI)), par.12

[735]Communication from the Commission of 3 March 2010, EUROPE 2020 A strategy for smart, sustainable and inclusive growth, COM (2010) 2020

[736] See note 734, par 9

[737] BERGKAMP L., KOGAN L., *Trade, the Precautionary Principle and Post-Modern Regulatory Process*, in *European Journal Risk Regulation*, 2013, p.507

[738] For a general overview on food innovation in the EU see ARGESE F., *Regulating food innovation and technology in the European Union*, in LUPONE A., RICCI C., SANTINI A. (eds.) *The right to safe food towards a global governance*, Torino, Giappichelli, 2013, p. 279-284. For a more scientific approach see MEISTERERNST A., DANIEL H., THRON M. (eds.) *Nanoparticles in food and cosmetics: Scientific and legal aspects*, in *European Food & Feed Law Review*, 2006, p. 69 ss.

On the one hand, in fact, the high EU standards in terms of food safety and environmental sustainability improve quality perception for EU products in non-EU markets.[739] On the other, the US and Canadian approach to risk assessment and management, could positively influence the EU in its future food policies, preventing it from adopting protective measures too burdensome for enterprises and too impermeable to scientific innovation[740].

Yet, the Fitness Check on the Regulation (EC) No 178/2002, completed by the Commission on January 2018 has clearly shown that several steps forward have been done[741] and that the legislative framework introduced by the General Food Law Regulation is 'fit for purpose'[742]. While contributing to the EU product safety recognition worldwide, the Regulation at stake has increased the value of the EU food trade by 72% over the past decade.[743]

Moreover, the Commission's Proposal for a new Single Market Programme emphasizes that it *"will strengthen the governance of the EU's internal market,*

[739] The EU is the biggest global exporter of food and drink, with total annual exports of EUR 85 billion, see note 733, p. 10

[740] In this sense, see EU Commission, Press release, Commission acts to boost trust in scientific studies on food safety, Brussels, 11 April 2018, available at http://europa.eu/ ; In particular, "certain negative impacts on innovation and trade in relation to authorization procedures are not directly attributed to the risk analysis principle as such, but to the specific design of those authorization procedures in specific EU food legislation"; for what concerns development in the field of animal cloning, the European Commission has presented two proposals for directives: Proposal for a Directive of the European Parliament and of the Council on the cloning of animals of the bovine, porcine, ovine, caprine and equine species kept and reproduced for farming purposes (COM(2013) 892 final) (*Cloning Technique Proposal*) and Proposal for a Council Directive on the placing on the market of food from clones (COM(2013) 893 final) adopted on 18 December 2013. (*Cloning Food Proposal*); for what concerns "novel foods" in general, as of 1 January 2018, the new Regulation (EU) 2015/2283 on novel foods is applicable. It replaces Regulation (EC) No 258/97 and Regulation (EC) No 1852/2001. The underlying idea of the recent developments in the field of "novel foods" and animal cloning is to foster innovation and scientific expertise while upholding human health protection

[741]Fitness Checks is a mechanism for policy evaluations, which provides an evidence-based critical analysis of the Union actions in respect of the achievement of their objectives. It is the first step of the Regulatory Fitness and Performance Programme (REFIT), initiated by the Commission, which contributes to the political agenda defined by President Juncker, giving priority to modernization and simplification of existing legislation. More information is available at https://ec.europa.eu/food/safety/general_food_law/fitness_check_en

[742]European Commission, Commission staff working document, The refit evaluation of the General Food Law (Regulation (EC) No 178/2002), Brussels, 15.1.2018, SWD (2018) 38 final

[743] Ibid. p. 93

supporting businesses', and in particular SMEs' competitiveness and promoting human, animal and plant health and animal welfare"[744].

In this regard, moving to the international dimension of food law, the EU trade policy can play a pivotal rule to make the global food governance reflecting the efficiency, effectiveness and coherence of EU food law.[745] Through the negotiation and conclusion of investments and trade agreements, the EU commits itself "*to uphold and promote its values in its relations with the wider world*"[746] and therefore, FTAs may represent the best tool to make European food standards a "model" worldwide.[747]

Nowadays, in fact, in a globalized world, "*greater connectivity is a European phenomenon too: the Eurozone crisis has highlighted both the density of interconnections within and outside the Union and the need to tackle the resulting economic problems through deeper integration*".[748] This is the reason why the 2015 trade policy strategy communication "Trade for All", has underlined so firmly the following objectives: reenergizing multilateral negotiations and designing an open approach to bilateral and regional agreements, including TTIP, exploring launching new investment negotiations with Hong Kong, Taiwan and South Korea, starting new ASEAN FTA negotiations with the Philippines and Indonesia.[749]

In light of this view, the DG trade's Strategic plan 2016-2020, among the general objectives pursued by the Juncker Commission, includes the following as the main ones: *New Boost for Jobs, Growth and Investment, A Reasonable and Balanced Free Trade Agreement with the U.S.*", and *the EU as a Stronger Global Actor*.[750] On the one

---

[744] European Commission, press release, *EU budget: New Single Market programme to empower and protect Europeans, Brussels*, 7 June 2018, p. 3
[745] ALABRESE M., *TTIP e agroalimentare. Prime riflessioni a margine delle proposte dell'Unione Europea nella negoziazione della "Trans-Atlantic trade and investment partnership* in *Rivista di diritto agrario,* 2016, fasc. 2, pt. 1, p. 217
[746] Article 3, par.5 TEU;
[747] CREMONA M., *Values in EU foreign policy*, in SCISO E., BARATTA R., MORVIDUCCI C. (eds.) *I valori dell'Unione Europea e l'azione esterna,* Torino, Giappichelli, 2016, p. 32
[748]*The European Union in a changing global environment. A more connected, contested and complex world*, EEAS Strategic Planning paper, 25 June 2015, p. 1
[749] Communication from the Commission of 14 October 2015, *Trade for all: Towards a more responsible trade and investment policy*, COM (2015) 497 / F1
[750] European Commission, DG Trade, *Strategic Plan 2016-2020*, p.9

hand, provided that a closer approach to the food sector is reached in the TTIP, the US, owing to its political and economic power, represents the best partner to shape global rules in the food sector and beyond. On the other, the idea to make EU a stronger global actor makes evident how "*trade policy is also a vehicle for promoting European and universal principles and values"*[751].

In this regard, as Aggestam argues, it is possible to observe "*a conceptual shift in the EU's role and aspirations from what it is to what it does, from simply representing a power of attraction and a positive role model, to proactively working to change the world in the direction of its vision*"[752].

Although necessary, this intention turns to be not sufficient for the food governance, since it has been shown that the extent to which safe and high-quality products can be provided in the EU are strongly influenced also by global economic trends.[753] Moreover, even when FTA, like CETA, has been concluded, it is not necessarily a guarantee of success, but it simply creates an opportunity which it's up to the economic operators and the States involved, to exploit for the best.

Therefore, even if it is true that the practical impact of an agreement may be assessed only as far as several years from its conclusion have passed, it is undeniable that through TTIP, CETA, current and future FTAs negotiated with Southeast Asian countries and the rest of the world, "*the EU may contribute to the formation of*

[751] Ibid, p. 14

[752] AGGESTAM L., *Introduction: Ethical Power Europe*, in *International Affairs*, Vol.1, 2008, p. 84. For what concerns the food sector more in detail, among the aims pursued by the DG Trade there is the will to promote fair and ethical trade schemes, to broader efforts to ensure responsible management of supply chains and to help consumers making informed choices; more information on the future nutrition policy are available at https://ec.europa.eu/food/safety/future/future-nutrition-policy_en

[753] European Commission, DG for Health and Consumers, *Scoping study Delivering on EU food safety and nutrition in 2050 - Scenarios of future change and policy responses, Final Report*, 20 October 2013, p. 29; According to the Report, relevant trends and uncertainties relate to: globalization of trade in food and feed; the increasing number of countries covered by free trade agreements; the emerging economies exporting more high added-value products and actively engaging in setting standards; global economic development; the increasing pressure on public finances from the crisis and expenditure on health and pensions.

international norms which it sees reflecting and giving concrete substance to its values"[754] and thus "*contributing to shape global food standards in the best way*".[755]

This Chapter has made clear the reciprocal influences of the WTO system on the EU legal framework and of the EU in the setting of international food standards.

On the one hand, food safety-related dispute before the WTO DSB, have often noted a departure, if not a failure, on the part of European regulatory choices in comparison to international ones.[756] On the other hand, one should not forget that since 2003[757] the EU is even a member of the Codex Alimentarius Commission, whose task, as underlined in Chapter 1, par. 3, is to develop international food standards that serve as a reference for the WTO SPS Agreement. Since this Codex represent a pillar for the international food trade, not only in the WTO multilateral trading system, but even for the SPS Chapters included in the FTAs negotiated worldwide, it is undeniable the powerful role of the EU in the elaboration of the Codex standards.[758]

Moreover, when it comes to bilateral free trade agreements between the EU on one side and relevant trading partners like the US and Canada, what shall be remarked is that trade relationship may represent a bridge between different approaches, a forum in which is about learning from each other and fulfilling regulatory gaps rather that winning or losing.

In this dialogue, nor the "*worldwide cultural significance of food and how people evaluate food safety*"[759] neither the fact that consumer protection is a fundamental right

[754] CREMONA M., *Values in EU foreign policy*, in SCISO E., BARATTA R., MORVIDUCCI C. (eds.) *I valori dell'Unione Europea e l'azione esterna,* Torino, Giappichelli, 2016, p. 17
[755]BATTAGLIA A., *Food Safety: Between European and Global Administration* in *Global Jurist*, Vol. 6, Issue 3, 2006, p.14
[756]On the issue see ECHOLS M. A., *Food Safety Regulation in The European Union and The United States*: *Different Cultures, Different Laws*, in *Columbia Journal of European Law*, Vol. 4, 1998
[757] Council Decision of 17 November 2003 on the accession of the European Community to the Codex Alimentarius Commission, 2003/822/EC
[758] The EU participation has also implied a modification of the procedures Manual of the Codex Commission for the addition of regional economic organizations
[759]PETROVETS K. A., *Moving towards harmonization of food safety standards: Role of the TTIP and TTIP Agreements*, in *Journal of Food Law and Policy*, 2016, p. 123

included in the EU Charter of Fundamental Rights[760] can be underestimated. At the same time, the EU attitude to precaution and the paramount importance of the protection of public health sometimes may lead to an overregulated framework to the detriment of economic considerations and business needs.

Therefore, the discussed FTAs may have the potential to let the US and Canada acknowledge that not everything has an economic value and can be appreciated in monetary terms, while teaching the EU that cost-benefit analysis and a science-based approach, even when it comes to food safety, are not as dangerous as they may seem.

Anyway, nowadays the lack of improvements in the multilateral trading system of the WTO and the increasing interconnection of markets and policies represent fertile soil for the development of a bilateral treaty network, which going beyond the WTO commitments, may play a crucial role for the global governance of food standards.

Therefore, the FTAs discussed in the present work, even if none of them can be currently analysed considering their concrete aftermaths, have an endless potential impact in terms of race to the top of food standards. Yet, the achievement of such expected result is not so obvious, since it relies upon the condition not only that regulatory tools are handled with care, but also that their negotiating processes are carried out and conclude thanks to a reciprocal strong political commitment to bridge countries and even food cultures.

[760]Article 38 ECFR: "Union policies shall ensure a high level of consumer protection"

Conclusion

The present work has made clear the role played by the EU Free Trade Agreements, on the one hand, as a side effect of the current crisis of multilateralism and on the other, as a vehicle to make EU food law a model worldwide.

For what concerns the first issue, as it has been pointed out, "*if the second half of the 20th century was the age of integration, of nations coming together and pooling sovereignty in pursuit of common goals, the 21st century looks increasingly as an age of drifting apart*"[761].

National movements reclaiming their sovereign powers, the increasing gap between national and international institutions, the emergence of new economic actors in the global scene[762] asking for renegotiation of the existing global governance setting, are more and more, undermining the role and legitimacy of multilateral and regional systems like the EU, the WTO, NATO and others.

"The current crisis of multilateralism has many faces: fewer multilateral treaties are being signed and ratified; some of the existing treaties are poorly implemented, and states increasingly reject the oversight of treaty obligations and monitoring of compliance by multilateral organisations"[763]

From this prospective, a further proof of the broader crisis affecting global multilateral institutions is given even by the organizations currently responsible for policing food safety, namely the WTO, the Codex Alimentarius Commission (CAC)[764] and the World Health Organization (WHO), which are failing to deliver on their declared objectives.

[761]EILSTRUP-SANGIOVANNI M., *The global crisis of multilateralism*, in *E-international relations*, 2016, available at http://www.e-ir.info;.
[762] The reference is to the BRICS, namely Brazil, Russia, India, China and South Africa
[763]LAZAROU E., *The future of multilateralism Crisis or opportunity?*, briefing by the European Parliamentary Research Service, May 2017, p.6
[764] The CAC is an international governmental body established on the basis of the two resolutions adopted by the Eleventh Session of the Food and Agriculture Organization of the United Nations (FAO) Conference in 1961 and the Sixteenth World Health Assembly (WHA) in 1963.

For what concerns the first one, chapter 1 has shown how the efforts undertaken in the WTO system to reduce obstacles and distortions to international trade, have led to an accelerated growth even of the food market. Yet, despite the undeniable acknowledgement of its achievements, the rising of trade protectionism, the 2008 financial crisis, the difficulties encountered in reconciling divergent interests between developed and developing countries, have made the future of the Doha Round uncertain.[765]

Even from a food safety prospective, the WTO regime does not encourage steps forward. As the analysis of the WTO SPS Agreement has made clear, its provisions require states nor to prohibit the export of unsafe food, neither to promote a positive implementation of international food standards. Moreover, chapter 2 has shown how EU food safety-related dispute before the WTO DSB, have often noted a departure, if not a failure, on the part of European regulatory choices in comparison to the international ones.[766] This situation shows how, owing to the EU precautious approach and given its attention to consumers' needs, the "scientific evidence requirement" set forth by the SPS Agreement, at the core of the above-mentioned disputes, is likely to turn into **"***an undue barrier to regulators who genuinely intend to protect public health rather than take protectionist measures*"[767].

Therefore, the shared hope that scholars have expressed regarding the future multilateral debate on food issues is that "*one will be able to say that the obstacle to the balanced performance of trade within the WTO is the absence of food safety, rather than national measures and international standards protection*"[768].

---

[765]ZUMPFORT W-D, *The Crisis of the WTO,* paper presented at the International Colloquium, *Global Freedom? The Future of International Governance*, organised by the Liberal Institute of the Friedrich Naumann Foundation, Potsdam, Germany 9-11 November 2007, p.8

[766]On the issue see ECHOLS M. A., *Food Safety Regulation in The European Union and The United States*: *Different Cultures, Different Laws*, in *Columbia Journal of European Law*, Vol. 4, 1998

[767]SYKES P., *Exploring the Need for International Harmonization: Domestic Regulation, Sovereignty, and Scientific Evidence Requirements – A Pessimistic View*, in Journal of international law, Vol. 3, 2002, p.353

[768]LUPONE A., *La governance della sicurezza alimentare nel contesto dell'organizzazione mondiale del commercio fra tutela degli scambi e basic human needs*, in RICCI C., SANTINI A., LUPONE A. (eds.) *La tutela multilivello del diritto alla sicurezza e qualità degli alimenti*, Giuffrè, 2013, p.146

For what concerns the Codex Alimentarius Commission, as underlined in chapter 1, food standards elaborated by the Codex Commission represent the reference standards, to assess the compliance of national sanitary and phytosanitary measures with the WTO SPS Agreement. Therefore, such presumption of conformity, while making the Codex standards "*de facto binding*", has also rendered the Codex Commission a "*quasi-legislator*". [769]

Through the years, owing to the WTO influence, the Codex has become a politicized forum[770], where its food safety standards are used more a tool to pursue trade objectives rather than to promote international food governance.[771] This why it has been argued that the "*its current institutional design is ill-suited to be an effective safeguard for global food safety*"[772].

The second pillar of the global food safety governance, namely the WHO, has been criticized too, for the fact that the difficulties encountered in the adoption of binding instruments, have more and more weakened its role.[773] Moreover**,** Taylor emphasizes how, given its expertise more in medicine than law, its policy is not so helpful "*to address global health problems in legal terms rather than in scientific ones*."[774]

---

[769]TRACHTMAN J. P., *The World Trading System, the International Legal System and Multilevel Choice*, in European Law Journal, vol.12, 2006, p. 469

[770]ALEMANNO A., *Trade in Food: Regulatory and Judicial Approaches in the EC and the WTO*, 2007, p. 262-263; see also SMYTHE E., I*n whose interests? transparency and accountability in the global governance of food: agribusiness, the Codex Alimentarius, and the World Trade Organization*, in CLAPP J., FUCHS D., *Corporate Power in Global Agri-food Governance*, Cambridge: MIT Press, p. 93-123. The author makes evident how in CAC meetings, "industry actors have been increasingly participating as the majority of observers"

[771] Owing to the enforceability of the WTO Agreements before the WTO DSB, countries have all the interests to vote in a manner that would advance their trade interests.

[772] For an overview on the current and future challenges of the Codex, see HULLER T., MAIER L. M., *Fixing the Codex? Global Food Safety Governance Under Review*, in JEORGES C., PETERSMANN E. (eds.) *Constitutionalism, multilevel trade governance and social regulation*, 2006, p. 267–99

[773] For a general overview on the role of the WHO see LIN C., *The Role of the World Health Organization in Global Food Safety Governance: A Preliminary Mapping of Its Normative Capacities and Activities*, in STEIER G., PATEL K., (eds.) *International Food Law and Policy*, 2016, p.1-18. At least since the adoption of the Framework convention on Tobacco Control in 2003, it has mainly adopted only non-binding instruments

[774] TAYLOR A. L., *Making the World Health Organization Work: A Legal Framework for Universal Access to the Conditions for Health*, in American Journal of Law and Medicine, vol. 18, 1992, p. 326

Therefore, for what concerns the international trade dimension of food law, the proliferation of FTAs may be the best solution to overcome the limits of these institutions and, in particular to set an alternative trading system to the WTO.

In this regard, among the opportunities that EU FTAs may provide in the food sectors, the following are the main ones.

First, the so-called "domino effect", which plays a crucial role for the development of a network of bilateral trade agreements, may produce a "diffusion effect" of the positive agri-environmental commitments undertaken by the parties involved in the FTAs.[775] In fact, "*the will of not being left behind with respect to the changes taking place in the world economy, brings states to copy the behaviour of others and to be more proactive in participating in the ongoing trading processes.*"[776] The more FTAs are concluded and the stronger is the economic and political leadership of the States involved, the more they can be "game-changers" of food safety rules and when one of the Parties is the EU, there is a lot to learn from its food policy.

In this regard, in fact, the second opportunity which these Agreements provide, is the possibility described in chapter three, to make EU food law a model worldwide.

"*By covering all stages of the food chain, prioritizing consumers' health protection, and referring to the European Food Safety Authority (EFSA) for scientific opinions, in fact, it is well done enough to be a model food law*"[777]. In particular, since its mission is to "provide scientific advice and scientific and technical support for the [EU] legislation and policies in all fields which have a direct or indirect impact on food and feed safety"[778] even the key role played by the EFSA shall not be underestimated.

---

[775] XING L., *Surprise under the table: Inspirations from the Canada-EU CETA for Enhancing Global Agri-Environment by FTAs*, in *Asper Review of International Business and Trade Law*, Vol. 13, 2013, p. 237

[776] WROBEL A., *Multilaterlism or bilateralism: the EU policy in an age of the WTO crisis*, in *EKONOMIA*, Vol. 92(3), p. 13

[777] LIN C., *Global Food Safety: Exploring Key Elements for an International RegulatoryStrategy*, in *Virginia Journal of International Law*, Vol. 51, No. 3, 2011, p. 657

[778] Regulation No 178/2002, Article 22, par.2

Scholars and experts, in fact, usually consider it as a good model of food safety decision-maker[779] which, in light of the essential similarities between the two systems, may even serve *"as a benchmark for evaluating the Codex Commission activities and as model of food safety governance for the edification of the Codex"*[780].

By providing independent, up-to-date scientific advice on food safety issues and ensuring accountability, transparency and openness in the scientific decision-making process, the EFSA structure may represent a model agency of risk assessment not only for the Codex, but even for third countries, like the US, where "*the resulting fragmented organizational and legal structure causes inefficient use of resources, inconsistent oversight and enforcement, and ineffective coordination*".[781]

Moreover, owing to the EU membership in the Codex and since the EFSA has recently participating as part of the EU delegation, it can play a proactive role in the definition of the Codex international standards, which, through EU FTAs may be further implemented.[782]

Yet, if at the multilateral level, the Codex represents the source of international food standards for the WTO, at the bilateral one it is regulatory cooperation, which if handled carefully, may represent the main tool thereby EU FTAs may contribute, to

[779]See, inter alia, GABBI S., *Dieci anni di EFSA: l'autorità europea al cuore del sistema europeo per la sicurezza alimentare*, in RICCI C., LUPONE A., SANTINI A. (eds.) *La tutela multilivello del diritto alla sicurezza e qualità degli alimenti*, Giuffrè, 2012, p.246-255

[780] LIN C., *The European Food Safety Authority in Global Food Safety Governance: A Participant, a Benchmark, and a Model*, in ALEMANNO A., GABBI S., (eds.) *Foundations of EU Food Law and Policy: Ten Years of the European Food Safety Authority*, Ashgate, 2014, p.30

[781]In the US, the competent food safety authorities are the U.S. Department of Agriculture (USDA) and the Food and Drug Administration (FDA). Along with them, there are other ten federal agencies with related tasks. For a critical analysis of the US food safety system see GAO, US Government Accountability Office, Food safety and security: *Fundamental Changes Needed to Ensure Safe Food*, 10 October 2011, available at https://www.gao.gov

[782] In this sense see ALEMANNO A., *The European Food Safety Authority at five*, in *European Food and Feed Law Review*, Vol.1, 2008, p. 2-24 and BARASSI M., *Equivalenza e mutuo riconoscimento nel commercio internazionale di prodotti alimentari: i casi di unione Europea e Cina*, in RICCI C., LUPONE A., SANTINI A., (eds.) *La tutela multilivello del diritto alla sicurezza e qualità degli alimenti*, Giuffrè, 2012, p. 190

reduce the existing gap between divergent food regulations while improving existing food safety standards.

The economic globalization of trade in food, in fact, makes clear how much regulatory deficiencies of a single state can produce "*spillover effects*", inevitably liable to pose significant health risks to many other parts of the world.[783] Therefore, considering that food-related hazards often happen on a global scale, even vigorous food regulatory systems, like EU food law, turn to be insufficient to address worldwide food safety crises.

This is even more true for what concerns developing countries, and EU trade partners, like Vietnam or the Philippines, which owing to ineffective and inadequate scientific and regulatory systems, still have a lot to learn, and in the case of EU FTAs, it's the EU itself the model. In this regard, since from the food safety prospective, developing countries are obviously more "*reactive rather than proactive*"[784], the more regulatory inputs they receive by their trade partners, the best will be the outcomes for their national food policies. This is why the relevance of the EUVFTA and of negotiations which other ASEAN countries shall not be underestimated.

This is even more true if one considers that the EU system of importation of food products coming from third countries, places on the foreign authority of that state, the duty to assess their compliance with EU food standards.[785]

Yet, this approach, rather than obliging the exporting State to set forth the same food standards provided by the EU regulations, is based the so-called "*conformity assessment equivalence*"[786]. Such system, which relies on certification and inspection

[783] LIN C., *Global Food Safety: Exploring Key Elements for an International RegulatoryStrategy*, in *Virginia Journal of International Law*, Vol. 51, No. 3, 2011, p. 665

[784]GONGAL NATH G., *International Food Safety: Opportunities and Challenges*, in SINGH S. P., *Food safety, quality assurance and global trade: concerns and strategies*, International Book Distributing Company, 2009, p. 89

[785] Relations whit third countries work differently than those between Member States, where mutual trust exists and disputes can be brought before the ECJ

[786] BARASSI M., Equivalenza e mutuo riconoscimento nel commercio internazionale dei prodotti alimentari: i casi di Unione Europea e Cina, in RICCI C., LUPONE A., SANTINI A., (eds.) *La tutela multilivello del diritto alla sicurezza e qualità degli alimenti,* Giuffrè, 2012, p. 191-192

processes, on the one hand, reducing the burden on EU authorities in carrying out sanitary controls at the frontiers is in line with the EU precautionary approach, on the other, using equivalence as an alternative tool to harmonization is in line with Article 4 of the SPS Agreement.[787]

Yet, owing to the financial and physical impossibility to check all the imported products, along with the existing inconsistencies among Member States in terms of EU food law implementation and enforcement, even the EU has to face the issue of insufficient border inspections, which consequently increases the risk for unsafe food products to be imported in the EU market.[788]

In this regard, one should not forget that new generation EU FTAs, in order "*to unburden the import procedures and eliminate redundant import requirements*", use to limit only to exceptional cases all the import checks and thus the main responsibility to ensure food safety is meant to be mainly on the exporting state.[789]

Therefore, on the one hand, the more exporting countries set forth effective and efficient food law systems, the less it is the likelihood that illness-causing products can be imported**,** on the other the more food standards are similar and the higher is the credibility of the exporting State's authorities the easier the trade relation will be.

This is the reason why regulatory cooperation, included in CETA and TTIP is critical for ensuring regional and global food safety: it represents an "*advanced form of*

[787]SPS Agreement Article 4, par.1 "Members shall accept the sanitary or phytosanitary measures of other Members as equivalent, even if these measures differ from their own or from those used by other Members trading in the same product, if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of sanitary or phytosanitary protection. For this purpose, reasonable access shall be given, upon request, to the importing Member for inspection, testing and other relevant procedures."
2. "Members shall, upon request, enter into consultations with the aim of achieving bilateral and multilateral agreements on recognition of the equivalence of specified sanitary or phytosanitary measures"
[788] WEBER W., *The road ahead for the European Food Authority*, in *The Lancet***,** vol. 358, 2001, p. 650
[789] PETROVETS K. A., *Moving towards harmonization of food safety standards: Role of the TTIP and TTIP Agreements,* in *Journal of Food Law and Policy*, 2016, p. 139

international dialogue on the causes of the regulatory differences while seeking to find common solutions to deal with them"[790].

Yet, as chapter 2 has shown every sector presents unique regulatory problems and for what concerns the EU transatlantic trade with US and Canada, the issues of GMOs, chemically-treated poultry and the use of growth hormones in meat production, no solutions have been found so far.

For what concerns the CETA, the evidence of such difficulties is given by Annex 5-D to its SPS Chapter, a "white paper" thereby the guidelines which Canada and the EU shall follow to determine, recognize and maintain equivalence of their sanitary and phytosanitary standards have "to be agreed at a later stage".[791]

Even in the framework of the TTIP negotiations, an unambiguous evidence is given by the current GMOs debate. On the one hand the US have expressed several times their unwillingness to accept an agreement including the rigid EU GMOs regulations, on the other the EU is even strengthening its laws in this sector.[792]

Therefore, understood this background and how chapter 3 emphasized, two are the main conditions upon which regulatory cooperation can work. The first one is the political will to reconcile different approaches and food cultures, even if only in the long-term and with undeniable efforts. The second one concerns the way how cooperation is carried out by the institutional bilateral bodies set forth in the FTAs and in charge to manage the joint regulatory activities: the joint EU-US management

[790] LESTER S., BARBEE I., *The challenge of cooperation: Regulatory Trade Barriers in the Transatlantic Trade and Investment Partnership*, in *Journal of International Economic Law*, 2013, p. 858

[791] CETA SPS Agreement, Article 5.6.2 points to the application of Annex 5-D

[792] Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015, amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory, entered into force 20 days after its publication in the Official Journal.

committee[793] and the Regulatory Cooperation Forum (RCF)[794] respectively in the TTIP and the CETA.

First, since on either side of the Atlantic "*a full scientific certainty almost never exists with respect to health risks*" the "*social aspect*" of food safety regulations shall be prioritized and thus regulatory cooperation "*necessarily has to be applied with regard to the priorities of the concerned population*"[795].

Second, the role of national Parliaments in such bodies has been questioned all over Europe, since, in either TTIP and CETA "*the power to identify and manage food safety issues has been transferred from national authorities to committees of experts*"[796]. Therefore, several scholars have underlined the importance to guarantee the possibility for the legislators to provide inputs into the regulatory dialogue[797]. Otherwise, without parliamentary involvement during the negotiations first and in the above-mentioned committees then, not only the enactment of any new and more stringent regulation, especially on the part the EU, can be made more difficult but a problem of legitimacy will come to the fore. As Petersmann emphasized, in fact, "*the inadequate parliamentary control of intergovernmental treaty-making must be compensated by stronger constitutional, participatory and "deliberative" democracy in the design and implementation of EU FTAs"*[798].

Third, a good regulatory cooperation is the one which, along with ensuring openness and transparency of its processes, takes into account the opinions of those private actors

[793] Commission's proposal for legal text on" Sanitary and Phytosanitary Measures (SPS)" in TTIP. It was tabled for discussion with the US in the negotiating round of (29 September-3 October 2014) and made public on 7 January 2015, Article 18
[794] CETA Chapter 21, Article 21.6
[795] COUVREUR A., *New Generation Regional Trade Agreements and the Precautionary Principle: Focus on the Comprehensive Economic and Trade Agreement (CETA) between Canada and the European Union* in, *Asper Review of International Business and Trade Law*, 2015, Vol. 15, p. 289
[796] FUNG S., *Negotiating Regulatory Coherence: The Costs and Consequences of Disparate Regulatory Principles in the Transatlantic Trade and Investment Partnership Agreement Between the United States and the European Union*, in *Cornell International Law Journal*, 2014, p. 138
[797] ALEMANNO A., *The Transatlantic Trade and Investment Partnership (TTIP) and Parliamentary Regulatory Cooperation*, European Parliament Policy Report, Brussels, 2014, p. 8
[798] PETERSMANN E-U., *Democratic Legitimacy of the CETA and TTIP Agreements?, RENSMAN T. (ed.) Mega-regionals Trade Agreements, 2017*, p. 37

who are better placed to detect the costs and inefficiencies that the existing regulatory divergences determine. Yet, as Chapter three has made evident, it seems that during the TTIP and CETA negotiations, rather than the civil society, it has been the business sector the main interlocutor and thus the risk of economic and lobbyist pressure in the future regulatory mechanism is less than unrealistic. Therefore, only a balanced inclusion of all the relevant stakeholders, namely "*consumers, distributors and producers, can lead to an efficient and pragmatic approach to deal with regulatory*.[799]

Moreover, since binding rules concerning risk regulation and regulatory cooperation are set nor under CETA, neither under the TTIP, the voluntary approach to cooperation and the inclusion of the so-called "Good regulatory practices", can represent a step forward for bridging divergent approach to food safety and to intensify the transatlantic dialogue [800].

Therefore, given these conditions regulatory cooperation may be the best tool to reduce and eliminate unnecessary and burdensome measures, while ensuring a high level of environmental sustainability and public health protection. Yet, since the outcomes of this mechanism can be appreciated only in the long term and at least so far, CETA is the only FTA provisionally applicable, only as time passes it will be possible to assess whether harmonization of food standard is going in the wrong direction and the fears expressed all over Europe are substantiated.

Moreover, another crucial issue, challenging and even worrisome, emerging from the exam of the EU FTAs, is the "*link between the protection of food safety and the regulation of investments and fair competition rules*"[801]. By direct foreign investments and established activities in different countries, multinational undertakings, which

[799] In this sense, see KRSTIC S., *Regulatory Cooperation to Remove Non-Tariff Barriers to Trade in Products: Key Challenges and Opportunities for the Canada-EU Comprehensive Trade Agreement (CETA), in Legal Issues of Economic Integration,* Vol. 39, No. 1, 2012, p. 27

[800]COUVREUR A., *New Generation Regional Trade Agreements and the Precautionary Principle: Focus on the Comprehensive Economic and Trade Agreement (CETA) between Canada and the European Union* in, *Asper Review of International Business and Trade Law*, Vol. 15, 2015, p. 286

[801] LUPONE A., *La governance della sicurezza alimentare nel contesto dell'organizzazione mondiale del commercio fra tutela degli scambi e basic human needs*, in RICCI C., SANTINI A., LUPONE A. (eds.) *La tutela multilivello del diritto alla sicurezza e qualità degli alimenti*, Giuffrè, 2013, p.146

dominate food production as a whole, "*are essential driving forces behind the changes in the global food system*"[802]. Since their aim is to maximize profit, their objectives tend to clash with the States' aim to safeguard public policies and the case of COOL described in chapter three made it clear. Moreover, since transnational agricultural and food corporations, use to target developing countries as sources of raw materials, EU FTAs like the one with Vietnam, "*may give a major contribution to strengthen their decision-making and enforcement capabilities in addressing food safety issues*"[803].

From a legal point of view, for what concerns the conclusion of tariff and trade agreements relating to foreign direct investments, the ECJ has played a pivotal role in determining the limits of the EU exclusive competence set forth by Article 207, par. 1 TFEU, in conjunction with Article 3, par.1, let. (e).

If the advisory opinion 1/94, on the Community membership in the WTO, represents a cornerstone for clarifying the division of competences between the EU and Member States for what concerns trade in services and the commercial aspects of intellectual property, the long-waited advisory opinion 2/15 does the same regarding the field of investments, in the FTAs framework.

In fact, by making clear that the EU is not endowed with exclusive competence, for what concerns the field of non-direct foreign investment and the regime governing dispute settlement between investors and States, the Court has make the qualification of negotiated or concluded FTAs in terms of "EU only" or "mixed agreements", easier. Current clarity about EU and Member States' competences and the unavoidable involvement of the latter in such matters, will allow to determine since the beginning,

[802]DETOMASI D. A., *The Multinational Corporation and Global Governance: Modelling Global Public Policy Networks*, in *Journal of business ethics*, 2007, p. 321 "transnational food corporations are able to source ingredients from different parts of the world, manufacture products in less expensive labor markets, and distribute those products worldwide".

[803] KEENER L., *Capacity Building: Harmonization and Achieving Food Safety*, in BOISTROBERT C., OH S., STIEPANOVIC A., LELIEVELD H., *Ensuring global food safety: exploring global harmonization*, Academic Press, 2009, p. 139-140

the applicable procedure as well as the actors to be involved in the negotiation, conclusion and ratification of the future FTAs.[804]

Thus, hereafter EU institutions will have to pay more attention to the considerations and fears put forward by Member states, while opening a broader dialogue with them, to avoid the *empasse* encountered so far regarding TTIP and CETA negotiations.

In this regard, while discussions about whether the TTIP will survive its ambitious go on, several critics argue that the request submitted by the Belgian government to the Court for an advisory opinion concerning the compatibility of the Investment Court System (ICS) provided by CETA[805] with the EU treaties, will have an undeniable impact, since it may represent the turning point for the future EU trade partnerships with third states, especially for what concerns the role of private investors.[806]

Therefore, if CETA is provisionally applied, waiting for national governments to ratify it, the TTIP, owing to the opposition and protests from the public opinion with the "Anti-TTIP" movements, has been, at least so far, set aside. The reason lies not only in the fact that a final agreement may not be capable of achieving a long-lasting compromise on food regulation policies[807], but also in the current trade policy of President Trump, which during the elections period has gained consents even thanks to the initiative to leave the negotiations.[808]

---

[804] In this sense see CALAMITA M. R., *Sulla competenza dell'Unione europea a stipulare accordi di libero scambio: il caso dell'EU-Singapore Free Trade Agreement*, in *DPCE Online*, v. 31, n. 3, 2017, p. 685-690, avaiable at http://www.dpceonline.it

[805] Chapter 8, section F

[806] CALAMITA M.R., *La «clausola ISDS» negli accordi commerciali di ultima generazione dell'Unione europea*, in *"Diritto pubblico comparato ed europeo,* fasc.2, 2017, p. 689

[807]WATTS J., *The Transatlantic Trade and Investment Partnership: An Overly Ambitious Attempt to Harmonize Divergent Philosophies on Acceptable Risks in Food Production without Directly Addressing Areas of Disagreement* in *North Carolina Journal of International Law*, Vol. 41, Issue 1, 2015, p. 133

[808] For a detailed overview on the trade policy pursued by the Trump administration, see LIGUSTRO A., *La politica commerciale del Presidente Trump: bilancio dei primi cento giorni*, in *Diritto pubblico comparato ed europeo*, fasc,2, 2017, p. 165-173

In conclusion, since the new generation of EU free trade agreements entails both opportunitities and challenges, the wish is that TTIP, CETA, and all the other current EU FTAs under negotiation, will be handled with care, not to bring EU food standards to the bottom, but to lead global food governance to the top.

BIBLIOGRAPHY

CHAPTER I

ACCONCI P., *Regulatory Cooperation Within International Trade Agreements of the European Union After the Treaty of Lisbon* in *Rivista di diritto internazionale*, 2016, fasc. 4, p. 1071-1099

ACCONCI P., *Riflessioni sull'accezione di qualità dei prodotti agroalimentari rilevante nel diritto dell'Unione europea*, in *Studi sull'integrazione europea*, 2016, p. 265-287

ALABRESE M., *Gli accordi commerciali mega-regionali e l'elaborazione del diritto agroalimentare* in *Rivista di diritto agrario,* fasc. 1, 2017, pt.1, p. 136-152

ALABRESE M., *TTIP e agroalimentare. Prime riflessioni a margine delle proposte dell'Unione Europea nella negoziazione della "Trans-Atlantic trade and investment partnership* in *Rivista di diritto agrario*, 2016, fasc. 2, pt. 1, p. 210-242

ANDERSEN H., *Protection of Non-Trade Values in WTO Appellate Body Jurisprudence: Exceptions, Economic Arguments, and Eluding Questions* in *Journal of International Economic Law*, 2015, p. 383–405

BALDWIN R. E., *Non-tariff Distortions of International Trade,* in *Journal of International Economics,* vol. 2, fasc. 3, p. 305-307

BASSU C., *Food Safety and reasonableness. Protection of the rights between precautionary principle and proportionality* in *Munus*, 2015, fasc. 2, p. 439-454

BECK U., *Risk society: Towards a new modernity*, London, 1992

BERNANRD C., *Competence review: The Internal Market*, 2013, p. 1-38

BEVILACQUA D., *I limiti della scienza e le virtù della discrezionalità: il principio di precauzione nel diritto globale* in, DELLA CANANEA G. (ed.) *I principi dell'azione amministrativa nello spazio giuridico globale*, Napoli, 2007, p. 2-40

BOCCHI M., *La dimensione internazionale del principio di precauzione e la sua applicazione nel diritto europeo e statunitense alla prova nel negoziato sul TTIP*, in *La Comunità Internazionale*, 2017, fasc. 2, p.255-284

BOLOGNINI S., *Food security, food safety e agroenergie*, in *Rivista di diritto agrario*, 2010, fasc.2, p. 308-333

BORGHI P. and Salvi L, *AlimentarEuropeo. Giurisprudenza della Corte di giustizia in materia alimentare*, in *Rivista di Diritto Alimentare*, 2012, fasc. 1, p. 9

BORGHI P., *Effects of the WTO on the cap and on national agricoltural law, particularly with regard to organic agriculture* in *Rivista di diritto agrario*, 2005, fasc. 2, pt.1, p. 292-31

BORGHI P., *Il regolamento n. 1782/2003 e le norme dell'Organizzazione mondiale del commercio (OMC/WTO)* in *Rivista di diritto agrario*, 2005, fasc. 1, pt. 1, p. 97-105

BORGHI P., *L'alimentazione come risorsa economica* in *Istituzioni del federalismo*, 2009, fasc. 2, p. 21

BORGHI P., *Le declinazioni del principio di precauzione* in *Rivista di diritto agrario*, 2005, fasc. 4, p. 711-722

BORGHI P., *Lo status di produttore e di consumatore di alimenti* in *Rivista di Diritto Alimentare*, 2008, fasc. 2, p. 4 e ss.

BORGHI P., *Tracciabilità e precauzione: nuove (e vecchie) regole per i prodotti mediterranei nel mercato globale* in *Diritto e giurisprudenza agraria e dell'ambiente*, 2004, fasc. 2, pt.1, p. 75-83

CALAMITA M.R., *Sulla competenza dell'Unione europea a stipulare accordi di libero scambio: il caso dell'EU-Singapore Free Trade Agreement* in *DPCE on line*, 2017, p. 685-690

CAPELLI F., *La sicurezza alimentare nell'Unione Europea e in Italia*, in *Diritto comunitario e degli scambi internazionali*, fasc. 4, 2016, p. 657-664

CHANG-FU L., *Risks, scientific uncertainty and the approach of applying precautionary principle*, in *Medicine and Law*, 2009, p.283-300

CHEYENE I, *Taming the Precautionary Principle in EC Law: Lessons from Waste and GMO Regulation*, in *Journal for European Environmental & Planning Law*, 2007, p. 468-483

CHING-FU L., *The WHO in Global Food Safety Governance: A Preliminary Mapping of Its Normative Capacities and Activities* in *International Food Law and Policy*, 2016, p. 30-45

COSTATO L., *Cibo e politica estera dell'UE* in *Rivista di Diritto Alimentare*, 2012, fasc. 1, p. 2

COSTATO L., *Il diritto alimentare: modello dell'unificazione europea* in *Rivista di Diritto Alimentare*, 2009, fasc. 3, p.1-3

COSTATO L., *La controriforma della PAC* in *Rivista di diritto agrario*, 2010, fasc. 2, pt.1, p. 369-378

COSTATO L., *La Pac [Politica agricola comune] riformata, ovvero la rinuncia a una politica attiva* in *Rivista di diritto agrario*, 2012, fasc. 2, pt.1, p. 393-404

COSTATO L., *Riforma della PAC e rifornimento dei mercati mondiali di prodotti agricoli alimentari* in *Diritto e giurisprudenza agraria, alimentare e dell'ambiente*, 2011, fasc. 2, pt.1, p. 87-91

COUTRELIS N., WEBER I., *The Free Movement of Goods Principle Facing the Protection of National Public Health in the Absence of Harmonised Legislation: The*

Case of Processing Aids Used in the Manufacture of Foodstuffs, in *European journal of Risk Regulation*, 2010, p. 263-265

DEL VECCHIO M., DI COMITE V., Da Doha a Bali il futuro dell'OMC tra nuove speranze e antiche questioni, in *La Comunità Internazionale*, 2014, p. 387 e ss.

DI TURI C., *La strategia commerciale dell'Unione europea tra "regionalismo economico" e multilateralismo: quale ruolo per gli accordi di libero scambio di nuova generazione* in *Studi sull'integrazione europea*, 2014, fasc. 1, p. 81-101

DU M., *Standard Review under the SPS Agreement after EC-Hormones II* in *International and Comparative Law Quarterly*, Vol. 59, Issue 2, 2010, p. 441-460

EUROPEAN COMMISSION, Enterprise and industry DG, *Free movement of goods: Guide to the application of Treaty provisions governing the free movement of goods*, 2010

GERMANO A., *Il commercio internazionale dei prodotti alimentari tra regole tecniche, norme giuridiche e stati sovrani: il caso dei prodotti biologici*, in *Rivista di diritto agrario*, fasc. 2, 2005 p. 272-292

GORMLEY L.W., *Free Movement of Goods and Their Use - What is the Use of It* in *Fordham International Law Journal*, Vol. 33, Issue 6, June 2010, p. 1589-1628

GOYENS M., *Consumers at the heart of the Transatlantic Trade and Investment Partnership (TTIP)*, in *BEUC*, p.1-8

GREEN N., HARTLEY T., USHER J. A., *The legal foundations of the Single European Market*, 1991, p. 52

HEYVAERT v., *Facing the Consequences of the Precautionary Principle in European Community Law* in *European Law Review*, 2006, p. 185-201

HUEI-CHIH N., *Can Article 5.7 of the WTO SPS Agreement Be a Model for the Precautionary Principle* in *A Journal of Law, Technology and Society*, Vol. 4, Issue 4 ,2007, p. 367-382

JIANG P., *A Uniform Precautionary Principle under EU Law*, in *Peking University Transnational Law Review*, Vol. 2, Issue 2, 2014, p. 490-518

KAYAERT G., *The European Market for Food Products* in *Food and Drug Law Journal*, Vol. 51, Issue 4, 1996, p. 717-726

LAOWONSIRI A., *Application of the Precautionary Principle in the SPS Agreement* in *Max Planck Yearbook of United Nations Law*, Vol. 14, Issue 1, 2010, p. 565-624

LORZ B., *EU Politics for Sustainable Consumption and Production - the Action Plan on Sustainable Consumption and Production and Sustainable Industrial Policy* in *Journal for European Environmental & Planning Law*, Vol. 6, Issue 3, 2009, p. 277-300

LUPONE A., RICCI C., SANTINI A., *The right to safe food towards a global governance*, Torino 2013, p. 229 e ss.

MCNELIS N., *EU communication on the precautionary principle*, in *Journal of International Economic Law*, 2000, p. 545-551

MONTANARI F. VARALLO C., PISANELLO D., *Food Fraud in the EU* in *European Journal of Risk Regulation (EJRR*), Vol. 7, Issue 1, 2016, p. 197-205

MONTANARO F., *Il parere 2/15 della Corte di Giustizia dell'Unione Europea e il futuro della politica commerciale dell'Unione* in *Osservatorio costituzionale*, fasc3, 2017, p. 1-11

MOSUNOVA N., *Are Non-Trade Values Adequately Protected under Gatt Art. XX* in *Russian Law Journal*, Vol. 2, Issue 2 2014, p. 101-113

NICHOLS P. M., *Trade without values*, in *Northwestern University Law Review*, vol 90, n 2, 1996, p. 30-74

O'CONNOR B., *Geographical indications in CETA, the Comprehensive Economic and Trade Agreement between Canada and the EU, in Rivista di diritto alimentare,Year* IX, numero 2, 2015, p. 1-11

OLIVER P., *Free movement of goods in the E.E.C.: under Articles 30 to 36 of the Rome Treaty,* European Law Centre, 1988

PERISIN T., *Balancing Sovereignty with the Free Movement of Goods in the EU and the WTO - Non-Pecuniary Restrictions on the Free Movement of Goods* in *Croatian Yearbook of European Law & Policy,* Vol. 1, p. 109-144

PETENIN L., *Clone Wars - The Challenges of Cloned Food in EU, US and WTO Law,* in *Environmental law review,* 2009, p. 246-263

REID E., *Risk Assessment, Science and Deliberation: Managing Regulatory Diversity under the SPS Agreement* in *European Journal of Risk Regulation*, Vol. 3, Issue 4, 2012, p. 535-544

RINZE J., *Free Movement of Goods: Art, 30 EEC-Treaty and the Cassis-de-Dijon Case-Law in Bracton Law Journal,* Vol. 25, p. 67-76

RUOTOLO G. M., *The latest generation of EU trade agreements and its relationships with the multilateral trading system* in *Studi sull'integrazione europea,* 2016, fasc. 2-3, p. 329-354

SAFRIN S., *Treaties in collision. The Biosafety Protocol and the World Trade Organization Agreements,* in *American journal of International law,* 2002, vol.96, Issue 3, p 610-612

SALMEH K. F., *How Does the European Union Solve Crises - With Solutions or by Avoidance - A Study of the Mad Cow Disease Crisis*, in *Georgia Journal of International and Comparative Law*, Vol. 27, Issue 1, 1998, p. 249-264

TERCHETE J.P., *Non-tariff barriers to trade,* in *Max Planck Encyclopedia of Public International Law,* 2014, P.1-8

THOMAS R. D., *Where's the Beef--Mad Cows and the Blight of the SPS Agreement*, in *Vanderbilt Journal of Transnational Law*, Vol. 32, Issue 2, 1999, p. 487-518

VAN DER MEULEN B., VAN DER MEULEN M., *European food law handbook*, Wageningen, 2014

VEINLA H., *Free Trade and the Precautionary Principle* in *Juridica International*, Vol. 8, 2003 p. 186-196

VOS E., *EU Food Safety Regulation in the Aftermath of the BSE Crisis*, in *Journal of Consumer Policy*, 2014, p. 10-20

WAGNER M., *The Future of SPS Governance: SPS-Plus or SPS-Minus*, in *Journal of World Trade*, 2017, p.445-469

WEATHERILL S., *Free Movement of Goods* in *International and Comparative Law Quarterly*, Vol. 50, Issue 1, January 2001, p. 158-167

WEILER J. H.H., *Epilogue: Towards a Common Law of International Trade*, in *The EU, the WTO, and the NAFTA-Towards a common law of international trade*, Oxford University Press, Oxford, 2000, p. 130-145

WIRTH D., *The role of science in the Uruguay Round and NAFTA Trade Disciplines*, in *Cornell International Law Journal*, 1994, No. 27, p.834

WTO-Agreement in *Columbia Journal of European Law*, Vol. 1, Issue 2 1995, p. 338-354

Chapter II

AGGESTAM L., *Introduction: Ethical Power Europe*, in *International Affairs*, Vol.1, 2008, p. 84

ALABRESE M., *TTIP e agroalimentare. Prime riflessioni a margine delle proposte dell'Unione Europea nella negoziazione della "Trans-Atlantic trade and investment partnership* in *Rivista di diritto agrario*, 2016, fasc. 2, pt. 1, p. 210-242

ALEMANNO A., *The regulatory cooperation chapter of the Transatlantic Trade and Investment: Institutional structures and democratic consequences*, in *Journal of International Economic Law*, 2015, p.631

ALGOSTINO A., *ISDS ("investor-state dispute settlement"), the heart of darkness of the "global economic governance" and the constitutionalism* in *Costituzionalismo.it*, 2016, fasc. 1, p. 76

APPLEGATE J. S., *The Precautionary Preference: An American Perspective on the Precautionary Principle, in Human and Ecological Risk Assessment: An International Journal* 2000, Vol. 6, Issue 3, p. 413-443

BERGKAMP L., KOGAN L., *Trade, the Precautionary Principle and Post-Modern Regulatory Process*, in *European Journal Risk Regulation*, 2013, p. 493-507

BOCCHI M., *The International Dimension of the Precautionary Principle and its Application in EU Law and in US Law in Light of the TTIP Negotiations* in *La Comunità internazionale*, 2017, fasc. 2, p. 255-284

BONORA G. *The "Novel Foods" in the Reg. (EU) No. 2015/2283 and insects: a possible evolution of the eating habits*?, in *Rivista di Diritto Alimentare*, 2016, fasc. 1, p. 42-54

BONORA G., *Sul difficile nodo della carne trattata con ormoni nel "Transatlantic trade and investment partnership (TTIP)*, in *Rivista di diritto agrario*, 2016, fasc. 1, pt. 1, p. 123-137

BRUNEAU J.C., *The Transatlantic Trade and Investment Partnership: A Threat to the International Trading System or the Panacea for the Economic Predicaments Faced by the EU and the USA* in *Connecticut Journal of International Law*, Vol. 33, Issue 1, 2017, p. 43-94

CALAMITA M.R., *La «clausola ISDS» negli accordi commerciali di ultima generazione dell'Unione europea*, in *"Diritto pubblico comparato ed europeo, Rivista trimestrale*" 2017, fasc.2, p. 307-340

CALVANO R., *Chi ha paura dei TTIP leaks? Brevi spunti sulla tutela dell'ambiente e di altri "beni comuni" tra prospettiva europea, internazionale e problemi di riassetto del regionalismo* in *Osservatorio costituzionale*, fasc. 2, 2016, p. 1-8

CARTER M., *Selling Science under the SPS Agreement: Accommodating Consumer Preference in the Growth Hormones Controversy* in *Minnesota Journal of Global Trade*, Vol. 6, Issue 2, 1997, p. 625-656

COUVREUR A., *New Generation Regional Trade Agreements and the Precautionary Principle: Focus on the Comprehensive Economic and Trade Agreement (CETA) between Canada and the European Union* in, *Asper Review of International Business and Trade Law*, 2015, Vol. 15, p. 265-292

CUSLI Expert Roundtable Report: *CETA, TPP, TTIP and the Canada-US Trade Relationship*, in *Canada-United States Law Journal*, vol. 39, p. 202-207

CZARNEZKI, JASON J., YANMEI, LIN, FIELD, CAMERON F., *Global Environmental Law: Food Safety & China* in *Georgetown International Environmental Law Review*, Vol. 25, Issue 2, 2013, p. 261-288

DEBLOCK C., RIOUX M., *From Economic Dialogue to CETA: Canada's Trade Relations with the European Union*, in *International Journal*, Vol. 66, Issue 1, Winter 2010-11, p. 39-56

DEBLOCK C., RIOUX M., *From economic dialogue to CETA: Canada's Trade Relations with the European Union*, in *International Journal*, 2011, p. 39-56

DEL VECCHIO A., *I tribunali internazionali, tra globalizzazione e localismi*, Bari, II ed., p. 76-85

DG TRADE, *The economic impact of the comprehensive economic and trade agreement, 2017*

DOLLE T, BRUNO G., *Mixed Feelings about Mixed Agreements and CETA's Provisional Application*, in *European Journal of Risk Regulation (EJRR*), Vol. 7, Issue 3 (2016), p. 617-622

EFSA, DG SANCO, *Risk perception and food safety: where do European consumers stand today?*, 2006, p. 1-5

EWING-CHOW M., *Southeast Asia and Free Trade Agreements: WTO Plus or Bust* in *Singapore Year Book of International Law*, Vol. 8, p. 193-206

FUNG S., *Negotiating Regulatory Coherence: The Costs and Consequences of Disparate Regulatory Principles in the Transatlantic Trade and Investment Partnership Agreement Between the United States and the European Union*, in *Cornell International Law Journal*, 2014, p. 445-470

GALLO D., NICOLA F., *The External dimension of EU investment Law: Jurisdictional Clashes and Transformative Adjudication*, in *Fordham International Law Journal*, 2016, p. 1090-1096

GALLO D., *Quale ruolo per l'arbitrato interstatale sugli investimenti nei recenti accordi sul libero commercio dell'Unione Europea?, i*n *Dialoghi con Ugo Villani*, Bari, p. 863-871

GALLO D., *Scope, extent and limits of the new system of the investment disputes resolution in the recent free trade agreements of the European Union* in *Il Diritto del commercio internazionale*, 2016, fasc. 4, p. 827-861

GORMLEY L. W., *Free Movement of Goods and Their Use - What is the Use of It*, in *Fordham International Law Journal*, 2010, p. 10-20

GOYENS M., *Consumers at the heart of the Transatlantic Trade and Investment Partnership (TTIP), BEUC Position statement* BEUC-X-2014-031, 6 May 2014, p. 1-8

HANSEN-KUHN K., SUPPAN S., *Promises and Perils of the TTIP: Negotiating a Transatlantic Agricultural Market, TTIP Series, Institute for Agriculture and Trade Policy (IATP),* October 2013, p. 1-19

HERWING A., *TTIP Regulatory Cooperation* in *European Journal of Risk Regulation (EJRR)*, Vol. 7, Issue 2, 2016, p. 262-268

JOHNSON P. M., *Comprehensive Economic and Trade Agreement between Canada and the European Union* in, *European Foreign Affairs Review*, Vol. 19, Issue 4 (December 2014), pp. 479-482

JOHNSON R., *The US-EU hormone dispute*, Congressional Research Service, 2015, CRS Report R40449

KLAMERT M., *The Principle of Loyalty in EU Law*, *Oxford,* 2013, p. 183-186

KRSTIC S., *Regulatory Cooperation to Remove Non-Tariff Barriers to Trade in Products: Key Challenges and Opportunities for the Canada-EU Comprehensive Trade Agreement (CETA),* in *Legal Issues of Economic Integration,* Vol. 39, No. 1, 2012, p. 3-28

KYSAR D. A., *Preferences for process/product distinction and the regulation of consumer choice*, in *Harvard Law Review*, 2004,

LEBLOND P., *The Canada-EU Comprehensive economic and trade agreement: more to it than meets the eye*, in *Policy Option Politiques,* 1 July 2010, p.74-78

LESTER S., BARBEE I., *The challenge of cooperation: Regulatory Trade Barriers in the Transatlantic Trade and Investment Partnership,* in *Journal of International Economic Law*, 2013, p. 847-867

LILLISTON B., *NAFTA renegotiation: What's at stake for farmers, food and the land,* Institute for Agriculture and Trade Policy (IATP), 15 August 2017, p. 1-16

LURIE A., KALININA M., *Protecting Animals in International Trade: A Study of the Recent Successes at the WTO and in Free Trade Agreements* in *American University International Law Review*, Vol. 30, Issue 3, 2015, p. 431-488

MANSOUR M., KEY S., *From farm to fork: the impact on global commerce of the new European Union Biothecnology Regulatory scheme*, in *The International Lawyer*, Vol. 38, No. 1, 2004, pp. 55-69

MATHIS J., *Multilateral Aspects of Advanced Regulatory Cooperation: Considerations for a Canada-EU Comprehensive Trade Agreement (CETA),* in *Legal Issues of Economic Integration*, Volume 39, Issue 1, p. 73-91

MATTHEWS A., *Food safety regulation in TTIP: much ado about nothing*, in *European Journal of Risk Regulation*, Vol. 7, Issue 2, 2016, p. 256-261

MAURO M. R. *Investimenti Stranieri*, in *Enciclopedia del diritto*, Annali, IV, Milano, 2011, p. 650-658

MAURO M. R., *Accordi internazionali sugli investimenti e Unione europea*, in *Studi sull'integrazione Europea*, Year V, 2010, p. 403-430

MAURO M. R., *Gli accordi bilaterali sulla promozione e protezione degli investimenti*, Torino, 2003

MELENDEZ-ORTIZ R., *Mega-regionals. What is going on?*, in *Mega.regional Trade Agreeents. Game changers or costly distractions for the World Trading system?* 2014, p. 1-50

MICCIARELLI G., *CETA, TTIP e altri fratelli: il contratto sociale della post-democrazia* in *Politica del diritto*, fasc. 2, 2017, p. 231-265

MULLER G., *The EU's Global Europe Strategy and the Liberalization of Trade in Legal Services: The Impact of the EU Free Trade Agreements in Asia*, in *Journal of World Investment & Trade*, Vol. 14, Issue 4, 2013, p. 727-762

PARK S. H., *Increasing FTA initiatives of East Asia and the World Trading System: Current state of play and policy options for the 21st Century,* in *ASIEN: The German Journal on Contemporary Asia*, vol 100, p. 44-70

PEDERSEN O. W., *From Abundance to Indeterminacy: The Precautionary Principle and its Two Camps of Custom*, in *Transnational Environmental Law*, Volume 3 Issue 2, 2014, p. 323-339

RAFFIOTTA E., *La protezione multilivello delle tipicità agroalimentari tra diritto globale e legislazione nazionale* in *Rivista di diritto pubblico italiano, comparato, europeo*, 2016, p.5-16

REHN T., TOURANGEAU W., SLATER A., HOLTSLANDER C., *Where in the world are GM crops and foods?*, Report of the Canadian Biotechnology Action Network (CBAN), 19 March 2015, p. 1-24

REVESZ R, *Environmental Regulation, Cost-Benefit Analysis, and the Discounting of Human Lives*, in Columbia Law Review, 1999, p.941-1017

SALVI L., *Alimentare & Globale* in *Rivista di diritto alimentare*, Anno VI, numero 4, 2012, p.1-3

SALVI L., *Alimentare &Globale* in *Rivista di diritto alimentare*, Anno VIII, numero 1 January-March 2014 p. 65-67

SCHROEDER W., Transatlantic Free Trade Agreements and European Food Standards, in *European Food and Feed Law Review (EFFL)*, Vol. 2016, Issue 6, 2016, p. 494-501

SCISO E, BARATTA R., MORVIDUCCI C*., I valori dell'Unione Europea e l'azione esterna,* Giappichelli, 2016

SCISO E., *Appunti di diritto internazionale dell'economia*, Giappichelli, III ed., 2017

SHARMA S. , IBRAHIM N., *How CETA Can Endanger Country of Origin Labelling,* in *IATP, Greenpeace and Canadian Centre for Policy Alternatives (CCPA),* 20 September 2017, 1-12

SHARMA S., IBRAHIM N., *CETA and the European opposition to cloning,* in *IATP, Greenpeace and Canadian Centre for Policy Alternatives (CCPA*), 20 September 2017, p. 1-8

SINCLAIR S., TREW S., MERTINS-KIRKWOOD H., *Canadian Centre for Policy Alternatives, Making Sense of the CETA: An Analysis of the Final Text of the Canada-European Union Comprehensive Economic and Trade Agreement*, 25 September 2014, p. 1-128

SYKES A. O, *The (Limited) Role of Regulatory Harmonization in International Goods and Services Markets*, in *Journal of International Economic Law*, 1999, Vol.2, Issue 1, p. 49–70

SYKES A.O., *Product Standards for Internationally Integrated Goods Markets*, Washington, D.C.: The Brookings Institution, 1995

The European Consumer Organization (BEUC), *Optimising Regulatory Coherence in TTIP: Need to Focus on Regulation, Not Regulations,* 2005, p.1-11

TREAT S. *CETA, Regulatory Cooperation and Food Safety,* in *IATP, Greenpeace and Canadian Centre for Policy Alternatives (CCPA),* 20 September 2017, p. 1-11

TREW S., *From NAFTA TO CETA: Corporate lobbying through the back door*, Canadian Centre for Policy Alternatives, Corporate Europe Observatory, Forum Umwelt und Entwicklung and LobbyControl, 9 February 2017, p. 1-20

VAN DER LOO G, WESSEL R. A., *The non-ratification of mixed agreements: legal consequences and solutions*, in *Common Market Law Review*, 2017, p. 1-28

VISANI S., *Modelli normativi a confronto: regolamentazione degli Ogm tra UE e USA in Rivista di diritto alimentare,* Anno IX, numero 3, 2015, p. 1-10

VON ENDT M., *Is TAFTA/TTP a Race to the Bottom in Regulatory Standards?: The Case of Hormone Treated Beef* in CARDOSO D. (ed.) *The Transatlantic colossus: global contributions to broaden the debate on the EU-US free trade agreement*, 2013, p.115-140

WATTS J., *The Transatlantic Trade and Investment Partnership: An Overly Ambitious Attempt to Harmonize Divergent Philosophies on Acceptable Risks in Food Production without Directly Addressing Areas of Disagreement* in *North Carolina Journal of International Law*, Vol. 41, Issue 1, 2015, p. 83-136

WEISS M., MIDDLETON J., SCHRECKER T., *Warning: TTIP could be hazardous to your health* in *Journal of Public Health*, Volume 37, Issue 3, 1 September 2015, p. 367–369

WIRTH D., *Geographical Indications, Food Safety, and Sustainability: Conflicts and Synergies, Bio-based and Applied Economics*, Vol. 5, No. 2, 2016, in *Boston College Law School Legal Studies Research Paper No. 359*

CHAPTER III

ALABRESE M., *Gli accordi commerciali mega-regionali e l'elaborazione del diritto agroalimentare* in *Rivista di diritto agrario*, fasc. 1, 2017, pt.1, p. 136-152

ARGESE F., *Regulating food innovation and technology in the European Union*, in LUPONE A., RICCI C., SANTINI A. (eds.) *The right to safe food towards a global governance*, Torino, Giappichelli, 2013, p. 279-284

AZOULAY L., *La securitè alimentaire dans la lègislation communautaire*, in BOURRINET J., SNYDER F. (eds.) *La securitè alimentaire dans l'Union europèenne*, 2003, Bruxelles, p. 31

BARASSI M., *Equivalenza e mutuo riconoscimento nel commercio internazionale di prodotti alimentari: i casi di unione Europea e Cina*, in RICCI C., LUPONE A., SANTINI A., (eds.) *La tutela multilivello del diritto alla sicurezza e qualità degli alimenti*, Giuffrè, 2012, p. 185-192

BARRIERE F., *Market Regulation and Consumer Protection* in *Osservatorio del diritto civile e commerciale*, 2017, fasc. 2, p. 519-532

BATTAGLIA A., *Food Safety: Between European and Global Administration* in *Global Jurist*, Vol. 6, Issue 3, 2006, p. 1-14

BELLONI M. P. *Nel limbo degli OGM: Tra divergenze interpretative e disciplinari, alla ricerca di un accordo fra Stati Uniti e unione Europea. E' questione di etichetta, ma anche di etica*, in *Rivista di diritto pubblico comunitario*, 2006, p. 30 ss.

BLUM G., *Bilateralism, Multilateralism, and the Architecture of International Law*, in *Harvard International Law Review*, 2008, p. 323-354

BOLOGNA S., *The trans-Atlantic trade and investment partnership and social rights: what kind of harmonization*, in *Il diritto del mercato del lavoro*, 2017, fasc. 2, pt. 1, p. 311-326

BORGHI P., *Passport please! WTO, Trips and the (serious?) question of geographical origin of foodstaff*, in *Studi in onore di Luigi Costato*, vol II, 2014, p. 1-10

BORGHI P., *Risk-related Communication and Food-related Communication: What Information to Consumers?* in *Rivista di Diritto Alimentare, 2011, fasc. 2, p. 7*

BRUNO F., *The accreditation of importers of food products in the USA*, in *Rivista di Diritto Alimentare*, 2014, fasc. 1 p. 17-21

COLE D. H., *Reconciling Cost-Benefit Analysis with the Precautionary Principle*, in *The Regulatory Review*, 5 March 2012, p. 1-3

COSTATO L., BORGHI P., RIZZIOLI S., *Compendio di diritto alimentare*, 2011, Padova, p. 156 ss.

COSTATO L., *Dalla food security alla food insecurity* in *Rivista di diritto agrario*, 2011, fasc. 1, pt. 1, p. 3-15

CREMONA M., *Values in EU foreign policy*, in SCISO E., BARATTA R., MORVIDUCCI C., (eds.) *I valori dell'Unione Europea e l'azione esterna,* Torino, Giappichelli, 2016, p. 3-35

DEWAAL C., BRITO, GONZALO R. GUERRERO, *Safe Food International: A Blueprint for Better Global Food Safety*, in *Food and Drug Law Journal*, Vol. 60, Issue 3, 2005, p. 393-406

EHRENREICH N., LYON, BETH, *The Global Politics of Food: A Critical Overview*, in *University of Miami Inter-American Law Review*, Vol. 43, Issue 1, 2011, p. 1-44

FERRARI M., IZZO U., *Diritto alimentare comparato*, Il Mulino, Bologna, 2012, p. 167-184

FORTIN N., *The US food safety Modernization Act: implications in transational Governance of Food safety, Food system sustainability, and the tension with free trade*, in *Duke Environmental Law & Policy Forum*, Vol. 25, 2015, p.314-334

GANGAHAR P., *Food Safety and Management System*, in SINGH S. P. (ed.) *Food safety, quality assurance and global trade*: concerns and strategies, 2009, p. 25-40

GABBI S., *Dieci anni di EFSA: l'autorità europea al cuore del sistema europeo per la sicurezza alimentare*, in RICCI C., LUPONE A., SANTINI A. (eds.) *La tutela multilivello del diritto alla sicurezza e qualità degli alimenti*, Giuffrè, 2012, p.246-255

GATHII J. T., *Food Sovereignty for Poor Countries in the Global Trading System* in *Loyola Law Review*, Vol. 57, Issue 3 (Fall 2011), p. 509-540

GEISTFELD M., *Reconciling Cost-Benefit Analysis with the Principle that Safety Matters More than Money*, in *N.Y.U. Law Review*,2001, Vol. 76, n. 1, p.115-189

GENCARELLI F., *Ultimi sviluppi della politica UE di qualità alimentare: "Pacchetto qualità" e origine dei prodotti,* in. RICCI C., LUPONE A., SANTINI A. (eds.) *La tutela multilivello del diritto alla sicurezza e qualità degli alimenti*, Giuffrè, p. 319-330

GONZALES C., *The Global Politics of Food* in *University of Miami Inter-American Law Review*, Vol. 43, Issue 1, 2011, p. 77-88

KERBER W., VAN DER BERGH R., *Mutual recognition in the global trade regime: lessons from the EU experience*, in LIANOS I., ODUDU O. (eds.) *Regulating trade in services in the EU and the WTO: trust, distrust and economic integration*, Cambridge University Press, 2012, p. 121-124

LAMBERT D., *Global Food Security: In Our National Interest* in *Journal of Food Law and Policy*, Vol. 8, Issue 1, 2012, p. 99-112

LESTER S., BARBEE I.., *The Challenge of Cooperation: Regulatory Trade Barriers in the Transatlantic Trade and Investment Partnership* in *Journal of International Economic Law*, Volume 16, Issue 4, 1 December 2013, p. 847–867

LIN C., *Food Safety Regulatory Cooperation in the US-EU Free Trade Pact*, in *Bill of Health*, Harvard Law School, 2013, p. 1-18

LIN C., *Global Food Safety: Exploring Key Elements for an International RegulatoryStrategy*, in *Virginia Journal of International Law*, Vol. 51, No. 3, 2011, p. 665-84

LIN C., *Mega-regional Transformation of Global Food Safety Governance: Normative Roots and Ramifications*, in SHIN-VI P., (ed.) *Governing Science and Technology under the International Economic Order: Regulatory Divergence and Convergence in the Age of Mega-regionals*, 2018, p. 232–257

LIN C., *Public-Private Interactions in Global Food Safety Governance, in Food and Drug Law Journal*, Vol. 69, Issue 2, 2014, p. 143-160

LIN C., *SPS-Plus and Bilateral Treaty Network: A Global Solution to the Global Food-Safety Problem?* in *Wisconsin International Law Journal*, Vol. 29, Issue 4, 2012, p. 694-734

LIN C., *The European Food Safety Authority in Global Food Safety Governance: A Participant, a Benchmark, and a Model*, in ALEMANNO A., GABBI S., (eds.) *Foundations of EU Food Law and Policy: Ten Years of the European Food Safety Authority*, Ashgate, 2014, p.30-57

LIN C., *The Role of the World Health Organization in Global Food Safety Governance: A Preliminary Mapping of Its Normative Capacities and Activities*, in STEIER G., PATEL K., (eds.) *International Food Law and Policy*, 2016, p.1-18

LUPONE A., *Balancing basic human needs and free trade in the WTO*, in LUPONE A., RICCI C., SANTINI A. (eds.) *The right to safe food towards a global governance*, Torino, Giappichelli, 2013, p.103-112

LUPONE A., *La governance della sicurezza alimentare nel contesto dell'organizzazione mondiale del commercio fra tutela degli scambi e basic human needs*, in RICCI C., SANTINI A., LUPONE A. (eds.) *La tutela multilivello del diritto alla sicurezza e qualità degli alimenti*, Giuffrè, 2013, p. 134-146

LUPONE A., RICCI C., SANTINI A., *The right to safe food towards a global governance*, Torino, Giappichelli, 2013

MEISTERERNST A., DANIEL H., THRON M., *Nanoparticles in food and cosmetics: Scientific and legal aspects*, in *European Food & Feed Law Review*, 2006, p. 69 ss

MELENDEZ-ORTIZ R., *Mega-regionals: What Is Going on?*, in *Mega-regional Trade Agreements. Game-Changers or costly Distractions for the World trading System?*, 2014, p. 1-50

NICHOLS P.M., *Trade Without Values* in *Northwestern University Law Review*, Vol. 90, Issue 2, p. 658-719

PEEL J., *Science and Risk regulation in International Law,* New York, Cambridge University Press, 2010

PERISIN T., *Transatlantic Trade Disputes on Health, Environmental and Animal Welfare Standards: Background to Regulatory Divergence and Possible Solutions* in *Croatian Yearbook of European Law and Policy*, Vol. 10, p. 249-268

PETROVETS K. A., *Moving towards harmonization of food safety standards: Role of the TTIP and TTIP Agreements,* in *Journal of Food Law and Policy*, 2016, p. 112-139

PITSCHAS C., *Transatlantic Trade and Investment Partnership (TTIP): The Devil in Disguise or a Golden Opportunity to Build a Transatlantic Marketplace* in *British Journal of American Legal Studies*, Vol. 5, Issue 2 (2016), p. 315-340

RICCI C., *International law as a meta-framework for the protection of the right to food*, in LUPONE A., RICCI C., SANTINI A. (eds.) *The right to safe food towards a global governance*, Torino, Giappichelli, 2013, p. 9-11

ROSSO GROSSMAN M., *Genetic Technology and Food Security* in *American Journal of Comparative Law Supplement*, Vol. 62, Issue 4 (Fall 2014), pp. 273-302

RUOTOLO G. M., *Gli accordi commerciali di ultima generazione dell'Unione Europea e i loro rapporti con il sistema multilaterale degli scambi*, in *Studi sull'Integrazione Europea*, 2016, p. 329-354

SANTINI A., *European food law ten years after Regulation (EC) No 178/2002*, in LUPONE A., RICCI C., SANTINI A., (eds.) *The right to safe food towards a global governance,* Torino, Giappichelli, 2013, p.251-258

SCHROEDER W., *Transatlantic Free Trade agreements and European Food standards*, in *European food and feed Law Review*, 2016, p. 494-501

SILVERGLADE B.A., *The WTO Agreement on Sanitary and Phytosanitary Measures: Weakening Food Safety Regulations to Facilitate Trade?, in Food & Drug Law Journal*, 2000, p. 517-20

TANGERMANN S., *Agriculture and Food Security: New Challenges and Options for International Policy*, E15 Expert Group on Agriculture, Trade and Food Security—Policy Options Paper, E15Initiative, World Economic Forum, 2016

THOMSEN B., *CETA's threat to agricultural markets and food quality*, in MERTINS-KIRKWOOD (eds.) *Making Sense of CETA: An analysis of the final text of the Canada-European Union Comprehensive Economic and Trade Agreement*, Berlin and Ottawa: PowerShift and CCPA, 2016

VON DER BURCHARD H., BARIGAZZI J., *Europe's Trade Fears: chlorine chicken, secret courts, in POLITICO,* July 2015, p.1

WIENER B. J., *Better Regulation in Europe*, in *Current Legal Problems*, 2006, p. 447-518

WIENER B., J., DOGERS M. D., *Comparing Precaution in the United States and Europe*, in *Journal of Risk Research*, 2002, p.317-349

XING L., *Surprise under the table: Inspirations from the Canada-EU CETA for Enhancing Global Agri-Environment by FTAs*, in *Asper Review of International Business and Trade Law*, Vol. 13, 2013, p. 211-240

ZILLER J., SALA-CHIRI G., *The EU multilevel food safety system in the context of the principle of conferral*, in LUPONE A., RICCI C., SANTINI A. (eds.) *The right to safe food towards a global governance*, Torino, Giappichelli, 2013, p. 229-237

GONGAL NATH G., *International Food Safety: Opportunities and Challenges*, in SINGH S. P. (ed.) *Food safety, quality assurance and global trade: concerns and strategies*, International Book Distributing Company, 2009, p. 89

KEENER L., *Capacity Building: Harmonization and Achieving Food Safety*, in BOISTROBERT C., OH S., STIEPANOVIC A., LELIEVELD H., *Ensuring global food safety: exploring global harmonization*, Academic Press, 2009, p. 139-140

CASE LAW OF THE EUROPEAN COURT OF JUSTICE

Judgment of the Court (Fifth Chamber) of 10 December 1985, *Criminal proceedings against Léon Motte*, C-247/84, EU:C:1985:492

Judgment of the Court (Fifth Chamber) of 6 May 1986, *Criminal proceedings against Claude Muller and others*, C-304-84, EU:C:1986:194

Judgment of the Court (First Chamber) of 15 November 2007, *Commission of the European Communities v Federal Republic of Germany*, C-319/05, EU:C:2007:678, par. 87

Judgment of the Court (Grand Chamber) of 10 February 2009, *Commission of the European Communities v Italian Republic*, C-110/05, EU:C:2009:66, par. 35

Judgment of the Court (Grand Chamber) of 14 December 2004, *Radlberger Getränkegesellschaft mbH & Co. and S. Spitz KG v Land Baden-Württemberg***,** C-309/02, EU:C:2004:799, par. 53

Judgment of the Court (Grand Chamber) of 27 January 2009, *Hein Persche v Finanzamt Lüdenscheid*, C-318/07, EU:C:2009:33, par. 29

Judgment of the Court (Second Chamber) of 7 March 1990, *H. Krantz GmbH & Co. v Ontvanger der Directe Belastingen and Netherlands State*, C-69/88, EU:C:1990:97, par.11

Judgment of the Court (Sixth Chamber) of 5 February 2004, *Commission of the European Communities v French Republic*, C-24/00, EU:C:2004:70, par. 52

Judgment of the Court of 10 December 1968, *Commission of the European Communities v Italian Republic*, Case 7-68, EU:C:1968:51

Judgment of the Court of 10 November 1982*, Walter Rau Lebensmittelwerke v De Smedt PVBA*, C-261/81, EU:C:1982:382

Judgment of the Court of 11 July 1974, *Procureur du Roi v Benoît and Gustave Dassonville*, C-8/74, EU:C:1974:82, par.5-9

Judgment of the Court of 11 July 2000, *Kemikalieinspektionen v Toolex Alpha AB*, C-473/98, EU:C:2000:379

Judgment of the Court of 12 July 1973, *Riseria Luigi Geddo v Ente Nazionale Risi*, Case 2-73, EU:C:1973:89

Judgment of the Court of 12 March 1987, *Commission of the European Communities v Federal Republic of Germany, C*-178/84, EU:C:1982:382

Judgment of the Court of 14 December 1979, *Regina v Maurice Donald Henn and John Frederick Ernest Darby*, C-34/79, EU:C:1979:295, par.21

Judgment of the Court of 16 June 1998, *A. Racke GmbH & Co. v Hauptzollamt Mainz*, C-79/78 *EU:C:1998:293*

Judgment of the Court of 20 February 1979, *Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein*, C-120/78, EU:C:1979:42, par. 8-14

Judgment of the Court of 22 March 1977, *Steinike & Weinlig v Federal Republic of Germany***,** C-78/76, EU:C:1977:52, par. 28-29

Judgment of the Court of 23 February 1995, *Criminal proceedings against Aldo Bordessa, Vicente Marí Mellado and Concepción Barbero Maestre*, C-358/93, EU:C:1995:54

Judgment of the Court of 23 November 1978, *Regina v Ernest George Thompson, Brian Albert Johnson and Colin Alex Norman Woodiwiss*, C-7/78, EU:C:1978:209

Judgment of the Court of 23 October 1997, *Commission of the European Communities v French Republic*, C-159/94, EU:C:1997:501

Judgment of the Court of 23 September 2003, *Commission of the European Communities v Kingdom of Denmark*, C-192/01, EU:C:2003:492, par. 45

Judgment of the Court of 24 November 1993, *Criminal proceedings against Bernard Keck and Daniel Mithouard*, Joined cases C-267/91 and C-268/91, EU:C:1993:905, par. 14-17

Judgment of the Court of 25 April 1985, *Commission of the European Communities v United Kingdom of Great Britain and Northern Ireland***,** C-207/83, EU:C:1985:161

Judgment of the Court of 25 January 1977, *W. J. G. Bauhuis v The Netherlands State*, C-46/76, EU:C:1977:6, par. 9

Judgment of the Court of 25 January 1994, *Angelopharm GmbH v Freie Hansestadt Hamburg*, C-212/91, EU:C:1994:21

Judgment of the Court of 25 July 1991, *Aragonesa de Publicidad Exterior SA and Publivía SAE v Departamento de Sanidad y Seguridad Social de la Generalitat de Cataluña*, Joined cases C-1/90 and C-176/90, EU:C:1991:327, par. 9-13

Judgment of the Court of 27 April 1994, *Municipality of Almelo and others v NV Energiebedrijf Ijsselmij*, C-393/92, EU:C:1994:171

Judgment of the Court of 27 February 1980, *Commission of the European Communities v French Republic*, C-168/78, EU:C:1980:51, p. 348

Judgment of the Court of 28 April 1998, *Nicolas Decker v Caisse de maladie des employés privés*, C-120/95, EU:C:1998:167

Judgment of the Court of 30 April 1974, *Giuseppe Sacchi*, C-155/73, EU:C:1974:40

Judgment of the Court of 5 February 1963, *NV Algemene Transport- en Expeditie Onderneming van Gend & Loos v Netherlands Inland Revenue Administration*, C-26/62, EU:C:1963:1, par. 9

Judgment of the Court of 5 March 1996, *Brasserie du Pêcheur SA v Bundesrepublik Deutschland and The Queen v Secretary of State for Transport, ex parte: Factortame Ltd and others*, Joined cases C-46/93 and C 48/93, EU:C:1996:79

Judgment of the Court of 5 October 1977, *Carlo Tedeschi v Denkavit Commerciale s.r.l*, C-5/77, EU:C:1977:144

Judgment of the Court (Third Chamber) of 13 September 2007, *Land Oberösterreich and Republic of Austria v Commission of the European Communities*, Joined cases C-439/05 P and C-454/05 P., EU:C:2007:510, par. 5

Judgment of the Court (Fifth Chamber) of 14 July 1983, *Criminal proceedings against Sandoz BV*, C-174/82, EU:C:1983:213, par. 16

Judgment of the Court (Fifth Chamber) of 30 November 1983, *Criminal proceedings against Leendert van Bennekom*, C-227/82, EU:C:1983:354

Judgment of the Court of 12 December 1972, *International Fruit Company NV and others v Produktschap voor Groenten en Fruit*, Joined cases 21 to 24-72, EU:C:1972:115, par. 14-15

EUROPEAN SECONDARY LAW

Regulations

Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers

Regulation (EC) No 852/2004 of the European parliament and of the council of 29 April 2004 on the hygiene of foodstuffs

Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin

Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organization of official controls on products of animal origin intended for human consumption

Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

Directives

Commission Directive 70/50/EEC of 22 December 1969 based on the provisions of Article 33 (7), on the abolition of measures which have an effect equivalent to quantitative restrictions on imports and are not covered by other provisions adopted in pursuance of the EEC Treaty

Council Directive 73/241/EEC of 24 July 1973 on the approximation of the laws of the Member States relating to cocoa and chocolate products intended for human consumption,

Council Directive 73/437/EEC of 11 December 1973 on the approximation of the laws of the Member States concerning certain sugars intended for human consumption

Council Directive 74/409/EEC on the harmonization of the laws of the Member States relating

European Parliament and Council Directive (EU) 2015/412 of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory

Decisions

Commission Decision 96/239/EC on emergency measures to protect against bovine spongiform encephalophathy, (1996) OJ L 78/47

ACTS OF EU INSTITUTIONS

Communication from the Commission of 12 December 2012, Regulatory Fitness, COM (2012) 746 final.

Communication from the Commission of 14 October 2015, Trade for all: Towards a more responsible trade and investment policy, COM (2015) 497 / F1

Communication from the Commission of 2 February 2000, on the Precautionary Principle, COM (2000) 1 final

Communication from the Commission of 2 October 2013, Regulatory Fitness and Performance (REFIT): Results and Next Steps, COM (2013) 685 final

Communication from the Commission of 30 April 1997, on consumer health and food safety, COM (97) 183 final

Communication from the Commission of 4 October 2006, Global Europe: competing in the world", Com (2006) 567

Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee - The Internal Market for Goods: a cornerstone of Europe's competitiveness, COM (2007) 0035 final

DG SANTE, Fitness Check of the General Food Law (Regulation (EC) No 178/2002) Brussels, 15.1.2018, SWD (2018) 37 final

European Commission, Commission staff working document, Action Programme for Reducing Administrative Burdens in the EU. SWD (2012) 423 final.

European Commission, Commission staff working document, The refit evaluation of the General Food Law (Regulation (EC) No 178/2002), Brussels, 15.1.2018, SWD (2018) 38 final

European Commission, Commission staff working document: A fitness check of the food chain, state of play and next steps, SWD (2013) 516 final

European Parliament resolution of 10 March 2009 on ensuring food quality, including harmonization or mutual recognition of standards (2008/2220(INI))

Green Paper on the general principles of food law in the European Union, COM (97) 176 Final.

White paper on food safety of 12 January 2000, COM (99) 0719 final

Acts of EU institutions concerning Free Trade Agreements

TTIP

(negotiated, but not signed yet)

European Commission, Initial EU position paper, *Trade Cross-cutting disciplines and Institutional provisions*, July 2013

European Commission, Initial EU position paper, *Technical barriers to trade*, July 2013

European Commission, EU paper, *Non-tariff issues in TTIP*, published on 21 March 2016

European Commission, *TTIP- EU proposal for Chapter: Regulatory Cooperation*, published on 21 March 2016

European Commission, *TTIP- EU proposal for Chapter: Good Regulatory Practices*, published on 21 March 2016

European Commission, *TTIP textual Proposal on Technical Barriers to Trade (TBT),* published on 7 January 2015

European Commission, *TTIP textual Proposal on Sanitary and Phytosanitary Measures (SPS),* published on 7 January 2017

European Commission, *TTIP textual Proposal on Customs and Trade Facilitation (CTF),* published on 7 January 2017

European Commission, *TTIP textual proposal on investment protection and investment court system*, published 12 November 2015

European Commission, *TTIP textual proposal on National treatment and market access for goods*, published on 21 March 2016

CETA

(signed on 30 October 2016)

Council of the European Union, *Comprehensive Economic and Trade Agreement between Canada, of the one part, and the European Union and its Member States, of the other part*, Brussels, 14 September 2016, 10973/16

Council of the European Union, *Joint Interpretative Instrument on the Comprehensive Economic and Trade Agreement (CETA) between Canada and the European Union and its Member States*, Brussels, 27 October 2016, 13541/16

Council of the European Union, *Comprehensive Economic and Trade Agreement between Canada, of the one part, and the European Union and its Member States, of the other part*, Brussels, 14 September 2016, 10973/16

Council of the European Union, *Council decision on the signing on behalf of the European Union of the Comprehensive Economic and Trade Agreement (CETA) between Canada, of the one part, and the European Union and its Member States, of the other part*, Brussels, 26 October 2016, 10972/1/16

Council of the European Union, *Council decision on the provisional application of the Comprehensive Economic and Trade Agreement (CETA) between Canada, of the one part, and the European Union and its Member States, of the other part, Brussels,* 5 October 2016, 10974/16

EUSFTA

(negotiated, but not signed yet)

European Commission, *EU-Singapore FTA: Chapter 4: Technical Barriers to Trade*, authentic text as of 18 April 2018

European Commission, *EU-Singapore FTA: Chapter 2-Annex A: Elimination of customs duties,* authentic text as of 18 April 2018

European Commission, *EU-Singapore FTA: Chapter 5: Sanitary and Phytosanitary Measures,* authentic text as of 18 April 2018

European Commission, *EU-Singapore FTA: Chapter 10-Annex A: List of Names to be Applied for Protection as Geographical indications in the territory of the Parties,* authentic text as of 18 April 2018

European Commission, *EU Singapore IPA Dispute Settlement,* authentic text as of 18 April 2018

EUVFTA

(negotiated, but not signed yet)

European Commission, *EU-Vietnam Free Trade Agreement Text - Annex 2-c: Reduction and/or elimination of customs duties*, agreed text as of January 2016

European Commission, *EU-Vietnam Free Trade Agreement Text - Chapter 7: Sanitary and Phytosanitary Measures*, agreed text as of January 2016

European Commission, *EU-Vietnam Free Trade Agreement Text - Chapter 12: Intellectual Property*, agreed text as of January 2016

European Commission, *EU-Vietnam Free Trade Agreement Text - Chapter 13: Dispute settlement*, agreed text as of January 2016

European Commission, *EU-Vietnam Free Trade Agreement Text - Chapter 16: Cooperation and Capacity building,* agreed text as of January 2016

ELECTRONIC BIBLIOGRAPHY

www.beuc.eu/.../beuc-x-2014-031_mgo_ttip_updated.pdf

http://trade.ec.europa.eu

https://www.politico.eu

www.weforum.org

https://www.politico.eu

https://www.theregreview.org

https://www.iatp.org

https://www.efsa.europa.eu