UNIVERSITY
OF TRENTO - Italy
Faculty of Law
Department of Legal Sciences

lawtech

The Trento Law and Technology Research Group
Student Paper n. 28

NEGOTIATION BASES AND APPLICATION PERSPECTIVES OF TTIP WITH REFERENCE TO FOOD LAW

GIOVANNI ACERBI

ISBN: 978-88-8443-563-7

NEGOTIATION BASES AND APPLICATION PERSPECTIVES OF TTIP WITH REFERENCE TO FOOD LAW

ABSTRACT

In recent months, the international headlines have turned their attention to the ongoing negotiations between European Union and United States within the Transatlantic Trade and Investment Partnership (TTIP). Actually, meetings between representatives of both the superpowers began more than two years ago, although their pace has not been very lively so far.

While officers of both the parties are currently preparing the thirteenth negotiation round, some scientific papers and academic articles have been already produced and their number is expected to rapidly grow.

This research investigates the implications of the treaty for food law. In this view, the purpose of the work is to highlight, with regard to the macro-sector of food law, the respective starting positions in both the legal systems and the possible outcomes of such an agreement.

KEYWORDS

TTIP, Food Law, Food Safety, Genetically Modified Organisms, Geographical Indications

About the Author

Giovanni Acerbi (e-mail: acerbigiovanni@tiscali.it), earned his J. D. in Law at the University of Trento under the supervision of prof. Umberto Izzo and prof. Matteo Ferrari (December 2015). The opinions stated in this paper and all possible errors are the Author's only.

NEGOTIATION BASES AND APPLICATION PERSPECTIVES OF TTIP WITH REFERENCE TO FOOD LAW

Giovanni Acerbi

INTRODUCTION

In recent months, the international headlines have turned their attention to the ongoing negotiations between European Union and United States within the Transatlantic Trade and Investment Partnership (TTIP). Actually, meetings between representatives of both the superpowers began more than two years ago, although their pace has not been very lively so far.

The purpose of this work is to highlight, with regard to the macro-sector of food law, the starting positions and the possible outcomes of such an agreement.

It is a consciously ambitious aim, especially considering the great confidentiality surrounding most of the negotiating texts, as well as the constant mutability of the global political and economic landscape. Yet, this does not impede to provide some suggestions concerning the final content of TTIP and its application stage.

In the following pages, the discussion is divided into four macro-areas, which contain further sectoral insights.

First of all, the main differences between the American and the European approaches will be outlined, retracing some important milestones in the history of international relations, with a particular attention for those between United States and European Union. At the same time, it will be examined the possible occurrence of issues related to sovereignty of European and American Parliaments with reference to the agreement.

Secondly, a wide overview on the respective regulations and competent bodies in matter of food safety will be carried out.

Then, it will be faced the complex and much debated topic of genetically modified organisms, which is a great cause for division between European Union and United States.

Finally, a deep focus will be dedicated to the geographical indications issue, which is a well-established institute in Europe but whose legal form is not recognized under the American intellectual property system, as well as under the multilateral international agreements. In doing so, a special section will be reserved for the case of wine products, which have a superior protection.

The work ends with some brief remarks about the impact of the treaty on the international trade agreements.

CHAPTER ONE

THE EUROPEAN UNION, THE UNITED STATES AND THE TTIP

In the following pages the reader can find a global comparison between the European concept of Food law[1], referring to the national laws as well as the regulation elaborated by the European Union institutions, and the American one, which is composed of a fragmented and evolving regulatory landscape too.

The reliability of a discussion focused on such a huge and wide topic, characterized also by a dangerous ambiguity around some of the keywords of the subject[2], is strictly related to a previous and cautious analysis of the differences between the two systems, not just the political and economic ones, but also the historical, cultural and sociological peculiarities that are the real basis of the importance and the social role which people confer to food.

So, it goes without saying that it is mandatory now to operate some preliminary distinguishes and to introduce a first representation of the points where the European and the American food law models are similar and different.

First of all, it is necessary to dispel a myth, or, better, to bring it back at its real proportions: the thought that, on the one hand, all the American food is junk food and, on the other hand, the European cuisine and its wine

---

1 To deeply analyze the peculiarities and the genesis of the contemporary food law, see M. FERRARI, U. IZZO, *Diritto alimentare comparato. Regole del cibo e ruolo della tecnologia*, il Mulino, 2012, pp. 19-32 and F. ALBISINNI, *Dalla legislazione al diritto alimentare: tre casi*, in "*Rivista di diritto alimentare*", 2007, n. 1.

2 For example, think about the concept of *food safety*, which concerns the reduction of food consumption-related risks above an acceptable threshold and not, as someone could wrongly believe, their complete elimination (which is obviously physically impossible). More, the same term could be confused with the concept of *food security*, which instead regards the sufficiency of food for an individual's adequate growth.

and food tradition are anytime and anywhere of high quality in every single place of the Old World is a very suggestive idea for the European reader, but it has not unique feedbacks and evidences, although it is certainly not unfounded.

For instance, the view that the braise of the piedmontese restaurant in Centallo is and always will be *better* than the beef steak offered by the Austin steak-house, although reassuring for the European restaurateur, is nowadays more and more in contrast with the global evolution of the food and agricultural sector. The same example, even more glaring, would be done comparing the Bordeaux chalice of the French mid-size winery with a glass of Californian Zinfandel.

The point is that, even though taste and sensibility in the food sector are a traditional strength of the European history, especially with regard to some particular Member States, which handle food as a real economic asset, the increasing globalization and the consequential mix of different cultures, mores and identities have led to make less evident as thought the quality gap between the two systems.

However, around thirty years ago, the famous oenological Judgment of Paris[3] already highlighted how much close were in quality (and how much difficult was to perceive the difference between) a series of French and American wines. This episode teaches us how and how much the food's brand, instead of its quality, influences the consumers' choices.

So, it could be better said that, *on average*, with equal product's typology, the millenary tradition of the European food sector still plays a relevant role on food quality and on consumer's perception: an evidence for this

---

[3] On May 24th 1976, the English wine merchant Steven Spurrier decided to organize a competition in order to demonstrate the superiority of French wines on the American ones. The jury, composed of 11 wine experts, was provided with some French Bordeaux together with some Californian wines of similar characteristics (but very much cheaper than the French ones). Then, it was the French and Californian Chardonnay's turn. The final verdict was really surprising, considering the fact that in both of the categories the winners were wines produced in Napa Valley.
On June 8th 2012 the University of Princeton reproduced a similar experiment, comparing to the French wines the corresponding white and red wines of New Jersey: this time too, even though the winners were French bottles, the American wines ranked among the top of the list.

process is the European trend to highlight the origin of food, not just in order to inform buyers about the salubrity of the product and the respect of sanitary standards along the entire supply chain, but also and above all to link the food product itself to a high value place, community and culture.[4]

Nonetheless, the importance of know-how and traditions is destined to decrease in a world where routes and channels let people to exchange information, products and services much faster than some decades ago. The mix of cultures and the temptation of the internationalization produce the side effect of leveling differences, conforming tastes, standards and products.

More, such a trend was generally analyzed in the past few years even with regard to its repercussions on human's health and on the health policies of the governments, particularly highlighting the danger of the abandonment of some key-foods for people's wellness among the modern nutrition habits of a large portion of citizens[5].

The challenge for the future will be therefore to succeed in holding together the markets and cultures integration with the protection of diversity and biodiversity.

---

[4] The concept of *terroir*, so ambiguous and apparently indefinite as precious in the wine&food marketing sector, tries to explain to the consumer the importance of the relation between an agricultural product and the territory which it comes from. Borrowed from the wine field, nowadays this word is widely used to indicate the strict interdependent relation existing between the typical product of a region (usually a small size one) and the territory itself, as a mixture of elements: not just the orographic, climatic and environmental ones, but also the social, historical and human factors. To go further on the topic, it is useful to remind the words of the geologist Dr. Carlo Ferretti during the seminary: *"La tutela giuridica del terroir nel mercato internazionale del vino: una riflessione interdisciplinare"* held at the Faculty of Law of the University of Trento on November 6th 2014: *"The word terroir identifies the characteristics of a precise and narrow wine zone, conferring it with identity and exclusivity."*

[5] F. DI TODARO, *La globalizzazione? Mangiamo tutti le stesse cose*, in *"La Stampa"*, July 21st 2014. The article recalls a study published by some environmentalists and scientists on *Proceedings of the National Academy of Sciences of the United States of America* (read the full text on www.pnas.org/content/111/11/4001.full) which alerts the public opinion about the progressive conformation of cultures and the consequential decrease of biodiversity all around the world.

Moving towards the food law rules in both the systems taken into account, it is necessary to premise to the exhaustive analysis of the following pages a basilar point as a compass for the reader to move across the field of comparative food law.

In the years, as a matter of fact, a line between the American bloc and the European's one has been marked, separating two opposite visions on one of the most important principles of food safety: the precautionary principle.

This concept, generally coinciding with the classical *"primum non nocere"*[6], is nowadays[7] considered the fulcrum of lots of medical, environmental and food regulations; it can be summarized in the argument that, in case of scientific uncertainty, where the safety of a particular product or conduct is disputed, it should be preferable to adopt the most cautious strategy of the available ones.

The basic choice of the precautionary principle's supporters ultimately consists in detecting the real positive aspects of a future decision, since the lack of evidence against that solution is not enough. This concept can be better explained with the thought *"absence of evidence is not evidence of absence"*, become popular thanks to the astronomer Martin Rees' phrase.[8]

Anyway, for the purpose of this work, it is enough to bring to light the impact of the adoption (or refusal) of the precautionary principle in food law.

---

6 The aphorism is usually wrongly linked to the Hippocratic Oath, which explains the same concept but uses different words; anyway, the phrase derives from the Greek classical thought.

7 The diffusion of such a classical concept in modern times is generally attributed to the English surgeon Thomas Innman's book, *Foundation for a new theory and practice of medicine* (1860), where the author recalls the so called British Hippocrates, Thomas Sydenham, a famous English doctor and thinker, who is most luckily the father of the aphorism *"primum est non nocere"*. The fancy Italian (*"meglio prevenire che curare"*) and American (*"better safe than sorry"*) transliterations are nowadays generally used outside of the medical and sanitary fields too.

8 The aphorism is usually attributed to another, more famous astronomer's pen, the American Carl Sagan, who actually simply used the Rees' phrase to explain an analogue concept within his book *Demon-haunted world: science as a candle in the dark*, Random House, 1995.

First, it has to be considered that the main regulatory text of the European food safety system, reg. 178/2002[9], points out at Article 7[10], among the general principles of the subject, the precautionary principle, opting for a precise position that, as the reader will see further, influences the European approach with regard to important aspects of food and agriculture policy, one above all the genetically modified organisms one[11].

To be honest, before reg. 178/2002, the Commission had already issued a communication[12] which not only underlined the importance of the precautionary principle as a parameter for the law-making process of European institutions, but, at the same time, tried to clarify the range and the scope of the principle.[13]

---

9 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.

10 The following is the full text of Article 7, Reg. (EC) 178/2002:
"Precautionary principle
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.
2. Measures adopted on the basis of paragraph 1 shall be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration. The measures shall be reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment."

11 See the Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, which represents one of the European fundamental laws concerning GMOs and whose content is informed to the food precautionary approach.

12 COM(2000) 1, Communication from the Commission on the precautionary principle, 2 February 2000.

13 We quote an eloquent recapping excerpt of the communication, concerning the *ratio materiae* extension of the precautionary principle: *"Although the precautionary principle is not explicitly mentioned in the Treaty except in the environmental field, its scope is far wider and covers those specific circumstances where scientific evidence is insufficient, inconclusive or uncertain and there are indications through preliminary objective scientific evaluation that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the chosen level of protection.*

Within the communication, it is retraced the principle's origin through a sort of representation of its evolution in both the European and the international field: with regard to the first field, the communication reminds that the precautionary principle was mentioned for the first time in a provision of the EC Treaty[14], which, albeit referred particularly to the environmental sector, is indisputably considered as applicable to the totality of areas in which European institutions are supposed to legislate on; regarding, otherwise, the international sources, it is recalled the World Charter for Nature of 1982[15] and the following Rio Declaration of 1992[16], asserting, according to an embraceable but surely not unanimous opinion, that in these fundamental acts the explicit acknowledgement of the precautionary principle, then accepted by SPS[17] and TBT[18] agreements promulgated by WTO in 1995[19], was already upheld.

---

[14] Treaty establishing the European Community, Maastricht, 7 February 1992. We report the original text of Article 130 R sub 2, then Article 174 sub 2: *"Community 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 Community. 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. In this context, harmonisation measures answering environmental protection requirements shall include, where appropriate, a safeguard clause allowing Member States to take provisional measures, for non-economic environmental reasons, subject to a Community inspection procedure."*
Nowadays, the provision survives, with the adequate linguistic adjustments due to the European bodies' name changes, but without variations of content, in Article 191 sub 2 of Treaty on the functioning of the European Union (TFEU).

[15] World Charter for Nature, United Nations General Assembly, 48ª plenary session, 28 October 1982. Article 11 (b) affirms: *"Activities which are likely to pose a significant risk to nature shall be preceded by an exhaustive examination; their proponents shall demonstrate that expected benefits outweigh potential damage to nature, and where potential adverse effects are not fully understood, the activities should not proceed."*

[16] Rio Declaration on Environment and Development, Rio de Janeiro, 14 June 1992. The 15th principle holds: *"In order to protect the environment, the precautionary approach shall be widely applied by States according 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."*

[17] Agreement on the application of Sanitary and Phytosanitary measures, Marrakech, 15 April 1994. We report the content of Article 5 sub 7: *"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*

In fact, as will be diffusely explained in the third chapter, Article 5.7 of SPS agreement has been the subject of rough disputes between the European Union, which tends to link the meaning of this provision to Article 7 reg. 178/2002's one, and countries like United States and Canada, which on the contrary oppose the identification of the rule with the precautionary principle as applied within the European system[20].

However, it should be noted that, in addition to regulatory provisions, a substantial contribution in defining the precautionary principle derived from some early European judges' decisions, which, far from merely apply the regulations, conferred practical significance to a mainly theoretical concept.[21]

Now, just consider that all the arguments presented above about the importance of the precautionary principle within the alimentary and safety policies' making-process are instead suffered, opposed and mostly rejected in the US.

As a matter of fact, during the years the United States, although signer of the above mentioned international conventions[22], has been embracing,

---

phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time."

18 Agreement on Technical Barriers to Trade, Marrakech, 15 April 1994.

19 On the extension of the SPS agreement: *"Sanitary measures deal with food safety and animal health aspects. Phytosanitary measures deal with plant life issues. This Agreement recognizes Member's rights to adopt SPS measures but stipulates than they must be based on science, should be applied only to the extent necessary to protect human, animal or plant life or health, and should not arbitrarily or unjustifiably discriminate between members where similar conditions prevail. The Agreement complements the TBT Agreement. It may be noted that this Agreement deals essentially with short-term direct health-related issues only; latent environmental and public health hazards of certain products and their trade effects are usually beyond the purview of this Agreement."*, P. K. RAO, *Environmental Trade Disputes and the WTO*, Pinninti Publishers, 2001.

20 See M. FERRARI, U. IZZO, *supra*, pp. 83-84.

21 To go further on the jurisprudential contribution to the definition of the precautionary principle's application area, see A. ALEMANNO, *The Shaping of the Precautionary Principle by European Courts: from Scientific Uncertainty to Legal Certainty*, in *"Valori costituzionali e nuove politiche del diritto"*, Halley, 2007, pp. 1-6.

22 It seems quite superfluous to remind that the US is part of the WTO.

despite some controversies within some sectors of public opinion, a diametrically opposite approach to the European one.[23]

The adoption of a different risk assessment mechanism[24], aimed at measuring political decisions on the basis of the related costs and benefits[25], has contributed to consider as unnecessary and, more, counterproductive, a suspicious attitude towards innovation, even where the absence of adverse effects is not scientifically ascertained[26].

Anyway, among the ranks of the European senior officials there is also who[27] tries to mitigate differences and to mediate the frictions arisen from

---

[23] One of the rare cases of an US court recurring to a concept quite close to what the precautionary principle, if adopted under the American regulation, would have imposed to follow to an American court, is represented by Maine v. Taylor, 477 U.S. 131 (1986), where the U.S. Supreme Court ruled in favor of the ban on baitfish importation imposed by the state of Maine: *"We agree with the District Court that Maine has a legitimate interest in guarding against imperfectly understood environmental risks, despite the possibility that they may ultimately prove to be negligible. The constitutional principles underlying the commerce clause cannot be read as requiring the State of Maine to sit idly by and wait until potentially irreversible environmental damage has occurred or until the scientific community agrees on what disease organisms are or are not dangerous before it acts to avoid such consequences."* See P. K. RAO, *supra*, p. 109.

[24] Technically we can consider this process as a unique mechanism, including the risk assessment phase as well as the risk management one. On the contrary, the European model tends to split them into two separated steps, to guarantee the highest level of independency to the scientific evaluation and research, confining the political influence only at the risk management phase.

[25] We refer to the *Cost-Benefit Analysis (CBA)* model, which tends to assign an economic value to each possible consequence of a particular regulation, then verifying the positive or negative balance among all the options on the table. To go further on the topic, see M. FERRARI, U. IZZO, *supra*, pp. 66-67 e C. R. SUNSTEIN, *Laws of fear. Beyond the precautionary principle*, Cambridge University Press, 2005.

[26] In such a context, the arithmetic sum resulting with the CBA method may already comprehend the eventual negative externalities provoked by the adoption of a certain decision or regulation, anticipating therefore the evaluation on its opportuneness. In other words, the adoption of the precautionary principle may lead to debase the CBA's scope, refusing to acknowledge its results.

[27] B. BONARDI, *TTIP: un'occasione da non perdere. Intervista esclusiva a Paola Testori Coggi*, ne "*Il fatto alimentare*", 7 August 2015. Coggi, former General Director for Health and Food Safety (DG SANCO, now DG SANTE), tries to attenuate the importance of the precautionary principle with regard to the European law-making process: *"It's such a theoretical principle, which is applied case by case. If exaggeratedly applied, it's hard to defend it also at WTO level. Practically, the European Union did not apply it so many times. […] The cases where we used it, deciding to ban due to the presence of scientific uncertainty, are really few: for instance, phthalates in toys for children and the partial ban on bisphenols in materials in contact with foods. In the field of pesticides, the ban on*

some international commercial events[28], furthermore in occasion of the negotiation and the future conclusion of such an important agreement as the TTIP.

Actually, the point is a little bit more complicated than it appears at first, for many reasons.

First of all, neither the American government and the related agencies nor the European institutions can indulge in the sureness of being completely right, discrediting the other's *modus operandi*: in fact, in its practical application, the precautionary principle does not lead to sure and definite results, but to nuanced situations, where a hundred percent scientific certainty cannot really be achieved anytime, in none of the two sides.

As other sectors of everyday life, the truth (if it exists and it is just one) is never all on one side, so the point is rather to understand the reasons and the possible benefits of such an approach, surely assessing its social, economic and environmental impact, but never claiming the right to bear absolute truths.[29]

Moreover, moving deeper into technical details, it has to be underlined that the litigations generated between European Union and United States with regard to the lawfulness of regulations based on the precautionary principle cannot be assessed without first taking into account some of the

---

certain products, namely the neonicotinoids, to protect the bees, was decided on the basis of scientific evidences, not of the precautionary principle. The authorization policy on GMOs is not based on the precautionary principle too, but on a strict scientific assessment."

[28] By way of example, see the controversies decided by the WTO Arbitration Panel concerning the usage of growth hormones in the livestock breeding (WT/DS26/R/USA, 18 August 1997) and the market release of genetically modified organisms (WT/DS/291, 7 February 2006). In both cases, the ban on importation established by the European Union was not considered lawful due to the lack of scientific evidence that substantiated the assumed harmfulness of the food.

[29] A similar criticism can be addressed, without discussing the merit of the more or less embraceable views whereby such a protest is conducted, to many of the movements, organizations and associations which started to fight against the closing of the TTIP, arguing however their convictions with hooligans' tones that may instead debase the reliability of the themes involved.

provisions of the international agreements: Article 2.2[30] of SPS Agreement, of which the mentioned Article 5.7 represents an exception, puts a series of procedural and substantive requirements upon those signatory states which want to introduce sanitary or phytosanitary measures in the country, as well as Article 5.1[31] of the same treaty requires in such situations to previously carry out a risk assessment procedure based on a scientific method.

As a matter of fact, the WTO Dispute Settlement Body has been more and more frequently asked to find solutions to cases that imply a preliminary effort to bring together the above mentioned provisions, in order to establish some fixed points about the evaluation of the lawfulness of these measures.[32]

In the light of these considerations, what has been identified as the *punctum dolens* of trade relations between European Union and United States, namely the precautionary principle, may become the key to understand the respective starting positions among the negotiation phase of an *omnibus* treaty, as the TTIP should be, and the possible perspectives of cooperation in conforming some important sectoral disciplines.

More pragmatically: how much the European Union and the United States central administrations may be willing to call into question their own policies, that so many hitches have caused in the international trade between the two blocks? And, supposing that a compromise will be

---

[30] Article 2 sub 2, Agreement on the application of Sanitary and Phytosanitary measures: *"Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5."*

[31] Article 5 sub 1, Agreement on the application of Sanitary and Phytosanitary measures: "*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."*

[32] M. FERRARI, U. IZZO, *supra*, pp. 82-84. Recapping, any sanitary and phytosanitary measure must be directed to protect human, animal or vegetal life, conformed to generally accepted scientific principles and cannot be discriminatory or constitute a restriction on trade.

reached, which currency of exchange could be considered as acceptable in view of a renegotiation of the respective food law regulations?

Taking into account that, obviously, the long and tricky gestation stage of TTIP, which, in the most optimistic expectations, may see the light by the end of 2017, has produced a lively, colorful debate among public opinion: surely, the highly divisive issues faced during these months won't be, once arrived to the closing stage of negotiation, a background aspect without remarks on the contents of the partnership.

Certainly, it is important not to make the mistake of considering the TTIP as an unusual and isolated event - so much to be afraid of its effects - in the relations between the United States and the European Union: it is, rather, the natural consequence of a long international process of regulatory harmonization, which had a relevant turning point at the beginning of '90s, when WTO was instituted.

1. THE IMPACT OF THE URUGUAY ROUND ON INTERNATIONAL RELATIONS

It has been mentioned above about the importance of two international agreements, in which the United States and the European Union took part, namely the SPS and the TBT ones.

It is hereby preferable, in order to better understand the subsequent focus on the genesis of TTIP, to try to reconstruct the context which led to the conclusion of such agreements, paying particularly attention to the bigger international picture within these agreements are included.

The SPS and TBT agreements are in fact the result of years of negotiations carried out during the famous Uruguay Round, which is nowadays considered as a historical turning point within the international trade landscape[33]: lasted from 1986 to 1994[34], it has the principal merit of

[33] SPS and TBT agreements are part of a large group of treaties negotiated during the famous Uruguay Round and finally signed in Marrakech in 1994. In fact, this

having replaced the GATT[35] with the newborn WTO and of having reformed the international rules on trade.[36]

It was, more precisely, the eighth round of the "multilateral trade negotiations"[37], which is the official name of the negotiations intervened from 1947 amongst the GATT[38] member countries now gathered in WTO.

It has to be noted that the United States, as well as seven[39] of the future twenty-eight members of the European Union took actively part in the international dialogue since the first round and that nowadays the European Commission is committed to representing the EU Member States and to protecting their stakes among the WTO.[40]

---

event coincided with the more global review of the General Agreement on Tariffs and Trade (GATT) of 1947 and with the transformation of the homonymous organization into the newborn World Trade Organization (WTO) starting from January 1st 1995. To go further on the topic, see P. BORGHI, *L'agricoltura nel trattato di Marrakech. Prodotti agricoli e alimentary nel diritto del commercio internazionale*, Giuffrè, 2004, chapters I and IV.

34 The negotiations directly linked to the Uruguay Round started on September 20th 1986 in Punta del Este, Uruguay and were definitively concluded with the signing of the Marrakesh Agreement on April 15th 1994.

35 GATT has to be intended here as an organization. The 1947 GATT Agreement is indeed nowadays in force and was updated by the homonymous agreement in 1994, following the Uruguay Round.

36 The results of negotiations, in which 123 countries took part, consisted in 20 international trade agreements.

37 The last round, currently ongoing due to the occurred stall, is the Doha Development Round, started in November 2001. The previous negotiation rounds have been the following:
- Geneva Tariff Conference, 1947;
- Annecy Tariff Conference, 1949;
- Torquay Tariff Conference, 1950-51;
- Geneva Tariff Conference, 1955-56;
- Dillon Round, 1960-61;
- Kennedy Round, 1963-67;
- Tokyo Round, 1973-79.

38 General Agreement on Tariffs and Trade (GATT 1947), Geneva, October 30th 1947. The treaty, intended to be enforced from January 21st following year, at the time included 23 countries.

39 Eight, considering the subsequent split of Czechoslovakia into Czech Republic and Slovakian Republic.

40 R. BENDINI, *Factsheet on the European Union - The European Union and the World Trade Organization*, May 2015.

However, the most relevant points for the purpose of this work are some important results of the Uruguay Round, namely: the creation of WTO as an organization suited to regulate the future commercial relationships and to resolve the related disputes as well; the protection of Geographical Indications under the TRIPs[41]; the conclusion of a set of agreements related to agribusiness, such as the Agreement on Agriculture (AoA)[42] and the SPS and TBT agreements.

The second one of these topics will be analyzed in detail in the fifth chapter, which is focused on Geographical Indications indeed.

As regards, instead, the creation of WTO, this is the arrival point of a long and troubled path started after World War II with the Bretton-Woods Conference[43], which first outlined the shape of the global trade, planning, together with a World Bank[44] and the International Monetary Fund (IMF)[45], an International Trade Organization (ITO).[46]

The ITO constitution project, apparently facilitated by the approval of the Habana Charter[47] by 53 States, definitively collapsed after the repeated refusals of the US Senate to ratify the agreement; thus, for a long time, the only landmark remained the GATT, which began to develop into a real organization rather than a mere treaty.

The WTO is therefore the realization of the ancient project of a common organization for global trade. In its founding text[48], it not only sets out the

---

41 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), Marrakech, April 15th 1994.

42 Agreement on Agriculture (AoA), Marrakech, April 15th 1994.

43 Bretton-Woods Conference, 1-22 July 1944, Bretton-Woods.

44 International Bank for Reconstruction and Development (IBRD). established on December 27th 1945 and currently incorporated into the United Nations (UN).

45 International Monetary Fund (IMF), established on December 27th 1945.

46 See N. NOTARO, *Judicial approaches to trade and environment: the EC and the WTO*, Cameron May, 2003, pp. 117-118.

47 Final Act of the United Nations Conference on Trade and Employment, March 24th 1948.

48 Agreement establishing the World Trade Organization, Marrakech, April 15th 1994.

operational rules to compel its international tasks[49], but it also lists among the annexes the above mentioned AoA, SPS, TBT, GATT[50], TRIPs[51] agreements.

Furthermore, it establishes also some "plurilateral trade agreements"[52], that are optional agreements for the WTO members, as for instance the International Bovine Meat Agreement.[53]

The general principles adopted by WTO in its policy formulation are essentially two[54]: the most-favoured nation's one[55], according to which the Member States agree to grant to products of other Member States conditions at least equal to those granted for similar products of other WTO countries, and the national treatment's one[56], according to which

---

49 *Ibid.*, Articles 1-16.

50 *Ibid.*, Annex 1A.

51 *Ibid.*, Annex 1C.

52 *Ibid.*, Annex 4.

53 The International Bovine Meat Agreement updated the previous Arrangement Regarding Bovine Meat and expected the implication of both the European Community and the United States. The WTO International Meat Council *de facto* opted to cease it and to delete it from the founding text from 1998.

54 See also N. BERNASCONI-OSTERWALDER, *Environment and Trade. A Guide to WTO Jurisprudence*, Earthscan, 2006, pp. 7-17.

55 Below, the content of the clause as provided within the updated text of Article 1 of GATT:
"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."

56 The clause is contained into the updated text of GATT as well as in the TRIPs' one, Article 3.1: "*Each Member shall accord to the nationals of other Members treatment no less favourable than that it accords to its own nationals with regard to the protection of intellectual property, subject to the exceptions already provided in, respectively, the Paris Convention (1967), the Berne Convention (1971), the Rome Convention or the Treaty on Intellectual Property in Respect of Integrated Circuits. In respect of performers, producers of phonograms and broadcasting organizations, this obligation only applies in respect of the rights provided under this Agreement. Any Member availing itself of the possibilities provided in Article 6 of the Berne Convention (1971) or paragraph 1(b) of Article*

products imported from a Member State cannot be subjected to fiscal and bureaucratic conditions that are disadvantageous compared to the domestic products' ones.

With regard, instead, to its organizational structure[57], at its top there is a General Director, who is assisted by a Secretariat; then there are also a Ministerial Conference, a General Council - flanked by the GATT, GATS[58] and TRIPs Councils - and a series of specific committees.

It is the General Council that, in a particular guise, carries out the delicate task of resolving the international disputes[59], working as a Dispute Settlement Body: very briefly, where the General Director cannot find a way to conciliate two Member States, the Council may set up a panel composed of international experts of the matter, against whose recommendations it is also possible to appeal to the Appellate Body; then, the Council decides - basically in a very aligned way[60] - on the experts' opinion or on the outcomes of the Appellate Body's report.[61]

It has to be considered, nonetheless, that the decisions of the Council are not effectively enforced: the losing nation is just required to withdraw its measures and to realign its policies with the treaties' provisions, but neither a punishment nor an enforcement procedure for the accomplishment of the decision is foreseen; for this reason, whereas the offending member would not implement the WTO recommendations

---

16 of the Rome Convention shall make a notification as foreseen in those provisions to the Council for TRIPS."

57 See Article 4 of basic text.

58 It is the General Agreement on Trade in Service (GATS), which together with GATT and TRIPs compounds the institutional architecture of WTO.

59 See Annex 2 of institutional treaty, which recalls the Dispute Settlement Understanding (DSU).

60 GATT 1947 stated that recommendations of the panel could have been rejected whereas even a single nation - included the losing one - would have opposed it in Council; GATT 1994 instead reversed the rule, applying the so-called reverse consensus mechanism, according to which the standing of the panel can be refused just in presence of unanimous dissent against it.

61 See also A. GOYAL, *The WTO and International Environmental Law. Towards Conciliation*, Oxford University Press, 2006, pp. 19-22. It has to be particularly noted that both the panel and the Appellate Body has a merely advisory-proactive function: it is indeed the Dispute Settlement Body the decision-making body committed to defining the dispute.

within a reasonable period of time[62], the Council may authorize the prevailing party to adopt retaliation measures.[63]

In the following pages some of the historical WTO decisions on disputes between the United States and the European Union will be examined in depth.

Instead, as regards the huge number of agreements arisen from the Uruguay Round, it is useful to focus the attention first of all on the AoA, SPS and TBT agreements, starting from the first of these.

The AoA has the main merit of having conferred a significant emphasis to agricultural issues on the international trade panorama, held that previously most of the GATT provisions were not applied to the agricultural sector, meantime providing a definition of what agricultural products are, accompanied by an exhaustive list.[64]

The agreement is structured around three fundamental pillars.

The first one is the almost complete elimination of non-tariff barriers[65] which reduce market access, *de facto* converting them into tariff equivalents.[66] Besides, members undertook the commitment of reducing

---

62 In any case it cannot be more than 15 months, as stated in Article 21.3 DSU.

63 Article 22.1 DSU: *"Compensation and the suspension of concessions or other obligations are temporary measures available in the event that the recommendations and rulings are not implemented within a reasonable period of time. However, neither compensation nor the suspension of concessions or other obligations is preferred to full implementation of a recommendation to bring a measure into conformity with the covered agreements. Compensation is voluntary and, if granted, shall be consistent with the covered agreements."* It has to be noted that whilst the provisions of GATT 1947 admitted retaliation just *una tantum*, after the authorization of the Council, now the procedure has to be considered automatic unless the Council presents a consolidated dissent.
This mechanism might be defined as a sort of indirect coaction remedy similar to the French institute called *astreinte*, nowadays embraced also within the Article 614-bis of Italian Civil Code.

64 See J. A. MCMAHON, M. G. DESTA, *Research Handbook on the WTO Agriculture Agreement*, Edward Elgar, 2012.

65 Non-tariff barriers (NBTs), opposed to the above mentioned Tariff barriers (BTs).

66 This is the so-called tariffication process, according to which non-tariff barriers are turned into tariff equivalents. See Article 4.2 AoA: *"Members shall not maintain, resort to, or revert to any measures of the kind which have been required to be converted into ordinary customs duties, except as otherwise provided for in Article 5 and Annex 5."*

tariffs on the basis of different parameters, according to the development level of each signatory country.[67]

The second pillar concerns, instead, the domestic support to agriculture and aims to distinguish the measures depending on their side effects on the market: on one side, there is a list of measures which are expressly permitted - the so-called Green Box[68] -; on the other side, there are measures included in the so-called Amber Box, which are prohibited or must be considerably reduced. Next to these two categories, there is a third series of measures falling within the so-called Blue Box, which are exempted from reduction if under the fixed threshold.

The third and last pillar is committed to decreasing the agricultural export subsidies[69], which must be reduced, still differently according to the member's economic development level, both in terms of total volume and in terms of budget expenditure.[70]

Few words have been spent in the previous chapter about the SPS and TBT agreements, which are closely related to the AoA.

To better understand the application area of both these treaties, it is helpful to look at the table[71] reproduced in the following page, which summarizes indeed the cases where it has to be applied the SPS agreement and those where instead it has to be applied the TBT's one.

---

67 See Article 4.1 AoA.

68 The Green Box comprehends measures directed to public services and sorts of income guarantees for producers.

69 See Article 9.1 AoA.

70 Article 9.2 AoA requires a reduction of 36% in value and 21% in volume within the following six years. These parameters are reduced to 24% in value and 14% in volume with regard to developing countries.

71 The table is available on WTO official website. It has to be particularly noted that the SPS agreement directly deals with scientific and environmental topics, while the TBT agreement is principally focused on international trade itself. For further information, see also B. VAN DER MUELEN, *EU Food Law Handbook*, Wageningen Publishers, 2014, pp. 90-96.

SPS measures typically deal with:	TBT measures typically deal with:
▪ additives in food or drink	▪ labelling of food, drink and drugs
▪ contaminants in food or drink	▪ grading and quality requirements for food
▪ poisonous substances in food or drink	▪ packaging requirements for food
▪ residues of veterinary drugs or pesticides in food or drink	▪ packaging and labelling for dangerous chemicals and toxic substances
▪ certification: food safety, animal or plant health	▪ regulations for electrical appliances
▪ processing methods with implications for food safety	▪ regulations for cordless phones, radio equipment, etc.
▪ labelling requirements directly related to food safety	▪ textiles and garments labelling
▪ plant/animal quarantine	▪ testing vehicles and accessories
▪ declaring areas free from pests or disease	▪ regulations for ships and ship equipment
▪ preventing disease or pests spreading to a country	▪ safety regulations for toys
▪ other sanitary requirements for imports (e.g. imported pallets used to transport animals)	▪ etc…

What is most important to underline about these treaties is the harshness of the disputes originated from their provisions. Not infrequently, in fact, the disputes which WTO has been supposed to resolve concerned the consistency of national measures with the rules of SPS and TBT agreements; furthermore, the SPS and TBT specific committees within WTO are constantly committed to reviewing and discussing the technical details of such regulations.

At the same time, subsequently to these agreements, some of the WTO members, namely several of the developing countries, claimed the need to further apply the equivalence principle[72], too many times trampled by the importing countries which, instead, usually require the adoption of the

[72] Article 4.1 SPS Agreement: *"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."*

same standards and procedures; other developing countries, instead, pointed the finger at the food safety requirements, considered as an obstacle to market access.

It can be said that, among the three of these agreements, the most problematic has been the one on sanitary and phytosanitary measures: in fact, as mentioned above, it contains three provisions, namely Articles 2.2, 5.1 and 5.7, which, together with Article 5.6[73], build up a very tricky microsystem, harbinger of various interpretations.

In particular Articles 2.2 and 5.6, specifically referred to the relation between science and precaution, actually are nothing but a sectoral declination of the necessity requirement provided in Article XX of GATT 1994[74], which lists the cases where the measures adopted by a member country are to be considered as allowed under the treaty itself. They are however provisions mostly committed to preventing the production of regulations and rules which could interfere with the international exchanges.

---

[73] The complete text of Article 5.6 says: *"Without prejudice to paragraph 2 of Article 3, when establishing or maintaining sanitary or phytosanitary measures to achieve the appropriate level of sanitary or phytosanitary protection, Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility."*

[74] See particularly letters (a), (b), (d) and (g): *"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;
[…]
(d) necessary to secure compliance with laws or regulations which are not inconsistent with the provisions of this Agreement, including those relating to customs enforcement, the enforcement of monopolies operated under paragraph 4 of Article II and Article XVII, the protection of patents, trademarks and copyrights, and the prevention of deceptive practices;
[…]
(g) relating to the conservation of exhaustible natural resources if such measures are made effective in conjunction with restrictions on domestic production or consumption;"
See also B. VAN DER MUELEN, *supra*, pp. 89-90.

In this regard, in fact, the entire Article 2 deals with the requirements that must be fulfilled by the national sanitary and phytosanitary measures in order to be considered as justified in the light of WTO agreements, particularly emphasizing the necessity of scientific principles supported by scientific evidence.[75]

Article 5 in its entirety is focused on the risk assessment process requested in order to establish whether a sanitary or phytosanitary measure is adequate or not; in particular, the much-debated Article 5.7 seems conferring legal recognition to the precautionary principle as an exception to the scientific evidence requirement.

Recapping, within the SPS agreement there would be a complex regulatory architecture which involves: Article 2.2, which enucleates the necessity requirement and requires the scientific evidence as well; Article 5.1, which lays down the risk assessment requirement; Article 5.6, which confirms and specifies the necessity criterion[76]; Article 5.7, which permits to undertake temporary measures in case of scientific uncertainty (*rectius*, of scientific evidence insufficiency).[77]

Further there will be space to discuss the actual cases which have led the WTO dispute settlement bodies to stress the meaning of such provisions; for now, this should be enough to understand the great breakthrough occurred 20 years ago in the international trade.

Then, let's go to briefly summarize what have been hitherto the milestones of the path which will lead, in the more or less near future, to the signing of TTIP.

---

[75] The point is extremely controversial also for the provision's formulation, which may appear referred just to the application step of such measures, and not instead to measures themselves. On the focus, see N. BERNASCONI-OSTERWALDER, *supra*, p. 151.

[76] A footnote related to Article 5.6 underlined in fact modalities to detect in which cases a measure does not interfere with trade more than necessary: *"For purposes of paragraph 6 of Article 5, a measure is not more trade-restrictive than required unless there is another measure, reasonably available taking into account technical and economic feasibility, that achieves the appropriate level of sanitary or phytosanitary protection and is significantly less restrictive to trade."*

[77] To go in depth on the topic see N. BERNASCONI-OSTERWALDER, *supra*, pp. 148-153, 258-264.

2. TTIP: A LONG ROAD YET TO BE CONCLUDED

The Transatlantic Partnership currently under negotiation has its roots in quite ancient times, considering the relatively young age of one of the two parties at the negotiation table, namely the European Union.

Officially, the negotiation on the treaty's contents began in the first half of 2013, when the President of the United States of America Barack Obama sooner[78] and the Council of the European Union later[79] conferred the mandate to talk with the respective counterparties.

Notwithstanding, as repeatedly pointed up by the detractors of such an agreement[80], the will to create a table to discuss the two commercial partners' standard and to remove the relevant barriers to trade in goods and services actually dates back to several years before, precisely to 1995, when the representatives of some of the largest European and American companies met together creating the TransAtlantic Business Dialogue (TABD). Such an organization, however arisen under the American and European institutions' auspices[81], represented nothing more than the effort of the large companies established on both the sides of the Atlantic Ocean to apply pressure in order to protect and promote their commercial interests. In a single word, lobby.[82]

---

[78] State of the Union Address, Washington, February 12th 2013: *"And tonight, I'm announcing that we will launch talks on a comprehensive Transatlantic Trade and Investment Partnership with the European Union - because trade that is fair and free across the Atlantic supports millions of good-paying American jobs."*

[79] *Directives for the negotiation on the Transatlantic Trade and Investment Partnership between the European Union and the United States of America*, Note from the General Secretariat of the Council of the European Union No 11103/13, declassified on October 9th 2014.

[80] See J. HILARY, *The Transatlantic Trade and Investment Partnership. A charter for deregulation, an attack on jobs, an end to democracy*, Rosa-Luxemburg-Stiftung, Brussels, March 2014.

[81] Note that TABD originated explicitly to operate as an official advisor board to the executive of both the commercial partners for their international trade. The US Secretary of Commerce Ronald Brown and the Vice-president of the European Commission Sir Leon Brittan actively took part in the association's first meeting, held in Seville in 1995.

[82] The word *lobby* is here to be understood without any meaning of negative value, but as a pressure action of stakeholders towards the competent legislative bodies.

This body, anyway, has been recently incorporated into the TransAtlantic Business Council (TABC)[83], which operates substantially as its antecedent, advising the American and European institutions on the discussions about international trade issues.

In this view, the start of the Joint EU/US Action Plan after the Madrid bilateral summit in 1995[84] reveals how much deep-rooted was the political will of the two giants in order to increase the economic integration.[85]

Parallel, in fact, with the launch of the Transatlantic Economic Partnership (TEP)[86] in 1998, the political leaders of both the formations had already tried to implement a common program for the economic cooperation which could increase the trade and the investments between the European Union and the United States. Such a program led in 2007 to the constitution of the Transatlantic Economic Council (TEC)[87], a co-chaired organism under the European and American institutions' control

---

Nowadays the lobbying process is integral part of the European and American decision-making process, and it does not concern only the private companies' business interests, but public interests pursued by consumers associations, local government and single politicians too. For a cautious stance in favor of TABD, see J. DUNOFF, *Globalization and the environment: the limits of the law*, in *"Security, Trade and Environmental Policy: a US/European Union Transatlantic Agenda"*, Kluwer Academic Publishers, 2000, pp. 196-198.

83 The TransAtlantic Business Council arose in 2013 from the merge between the TransAtlantic Business Dialogue and the European-American Business Council (EABC), which had previously replaced the European Community Chamber of Commerce in the United States.

84 *The New Transatlantic Agenda and the Joint EU-US Action Plan*, EU-US Summit, Madrid, December 3rd 1995.

85 See G. FEKETEKUTY, *The next generation of world trade policy development*, in *"Security, Trade and Environmental Policy: a US/European Union Transatlantic Agenda"*, Kluwer Academic Publishers, 2000, pp. 123-124, where it is also highlighted one of the largest obstacles to the creation of a EU-US free trade area, namely the fear that a similar agreement could undermine the global primacy of WTO.

86 The Transatlantic Economic Partnership, by most denoted as the first forerunner of the TTIP, was promoted in occasion of the London summit on May 18th 1998 and became the global action plan for the trade between the European Union and the United States for the next twenty years. Its goal was to create an advisory board to address the cooperation policies of both the partners.

87 The Transatlantic Economic Council was born on April 30th 2007 following the agreement between the President of the United States of America George W. Bush, the President of the Council of the European Union Angela Merkel and the President of the European Commission José Manuel Barroso.

and committed to conveying and coordinating the large European and American companies' needs.

During these years, some failed attempts to close agreements on global trade have been collected, one for all the WTO Doha Development Round, started in 2001 and apparently definitively collapsed in July 2008.[88]

Therefore, it's evident that the repeatedly proposed project of a Transatlantic Free Trade Area (TAFTA)[89] has been revised and refined year by year by the international-play actors, which could experience with the difficulties in reaching an agreement on some sectors and with the relative community of interests and political desires on other ones.

Thus, the so discussed TTIP is the son of this long and complex story and, although only recently brought to the fore by medias, when the twelfth negotiation round has already passed[90], it is on the both parties politicians' mind since long time ago.

---

[88] On July 29th 2008, at the WTO headquarters in Geneva, the negotiation shortly collapsed after a stall due to the impossibility to reach an agreement between India, China and United States with regard to the support measures to small farmers in case of imports surge or price fall. The European Union's position, at first quite aligned to the American's one, was to consider the conference a "collective failure".

[89] Since from the last decade of the last century there have been lots of politicians, American as well as European, who have pushed in direction of an agreement between the two super powers which could generate mutual economic gains. One for all, the German Chancellor Angela Merkel, proud supporter of a trade cooperation program between European Union and United States, who in January 2007 did not hesitate to express herself as following: *The different approaches to regulation on the two sides of the Atlantic create unnecessary transaction costs. We can reduce these costs. Our goal should be the creation of structures similar to those of an internal market."* Complete text available at www.spiegel.de/international/trans-atlantic-free-trade-merkel-calls-for-closer-eu-us-cooperation-a-462160.html.

[90] The twelfth negotiation round was held in Brussels from 22nd to 26th February 2016. The previous negotiations were held:
- from 7th to 12th July 2013 in Washington;
- from 11th to 15th November 2013 in Brussels;
- from 16th to 21st December 2013 in Washington;
- from 10th to 14th March 2014 in Brussels;
- from 19th to 23rd May 2014 in Arlington;
- from 13th to 18th July 2014 in Brussels;
- from September 29th to October 3rd 2014 in Chevy Chase;
- from 2nd to 6th February 2015 in Brussels;
- from 20th to 24th April 2015 in New York;
- from 13th to 17th July 2015 in Brussels;
- from 19th to 23rd October 2015 in Miami.

Moreover, the TTIP is not the unique international treaty which the parties are working on: on one side, the European Union is going to close a similar trade agreement with Canada, namely the Comprehensive Economic and Trade Agreement (CETA)[91]; on the other, the United States is making effort to carry out the negotiation of the Trans-Pacific Partnership (TPP)[92], a huge economic agreement amongst a dozen of countries of the Pacific Rim.[93]

Last but not least, a purely political annotation: since the election for the replacement of the European Parliament in May 2014 and the related changes at the top of the European bodies[94] have concurred in lengthen the timing of TTIP negotiation, on the American side the Obama administration, which infused a significant effort in promoting the

---

The mere fact that in the United States the negotiation places have been various, while in the European Union they have been always taken place at the executive headquarters may be differently interpreted: as a way to cut costs for the European Union or due to the fear of the possible consequences if the panel would have met in various Member States, as an evidence of the fragility of the European executive, which is higher than the negotiating partner's one.

91 The CETA negotiations date back to 2009 and definitively ended in August 2014. Taking into account the time needed for the global review of the text and for the approvals required by the European and Canadian legislatives bodies, it probably may enter into force from 2016. The complete and consolidated text of the agreement was released on September 26th 2014 at http://trade.ec.europa.eu/doclib/docs/2014/september/tradoc_152806.pdf.

92 The TPP was to be intended as an expansion of the previous *Trans-Pacific Strategic Economic Partnership Agreement (TPSEP* or *P4)* between Chile, New Zealand, Singapore and Brunei signed in 2006, but it has been radically transformed by the acceleration imparted by the admission of new countries into the negotiations.

93 The countries which currently participate to the negotiations are Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, United States and Vietnam. An official interest to join the group has been declared by Colombia, Philippines, South Korea, Taiwan and Thailand.
It may be noted the temporary absence to the negotiation table of China, that has been differently interpreted by some international columnist: David Pilling, Financial Times (*It won't be easy to build an 'anyone but China' club*) did not hesitate to define the TPP as an expedient intended exclusively to isolate China, but Mireya Solis, Brookings Institutions (*The Containment Fallacy: China and the TPP*) objected that actually China could easily accede to the agreement in the future. Surely, the absence of China is, for the moment, one less hurdle to think about for the United States.

94 The European elections held from 22nd to 25th May 2014 led to the reconfirmation of the PPE outgoing majority within the European Parliament. Subsequently, Jean-Claude Juncker became the President of the European Commission and Cecilia Malmström replaced Karel De Gucht as European Commissioner for Trade.

international agreements' season[95], can no longer afford an ulterior delay of the partnership's closing deadlines.[96]

As a matter of fact, while in all probability the United States will succeed in taking home the TPP within the first half of 2016, the negotiation progress on TTIP is instead more backward, and there is the serious risk of facing the hot topics only in the second half of 2016[97], in the middle of the election campaign or, worse, with a new tenant in the White House.[98]

3. THE NEGOTIATING MANDATE: DELEGATION AND POOLED SOVEREIGNTY

This section will deal with some legal and political issues which not only sustain the architecture of TTIP, but represent as well effective interpretations to better understand the European and American institutional frameworks.

---

95 As noted, the ambitious goal to conclude some important agreements, TTIP and TPP overhead, within the end of his term, has been often recalled in President Obama's official speeches.

96 In order to boost the negotiation process, the European Union and the United States have so agreed to fix two additional rounds before the summer break, as reported by the the European Union Chief Negotiator Ignacio Garcìa Bercero in a Statement following the conclusion of the 12th TTIP negotiation round. To better understand both the parties' worries about the negotiation schedule and the risk of failures, see H. VON DER BURCHARD, *Last chance for transatlantic trade pact*, in *"Politico"*, April 11th 2016.

97 This is a useful key to understand the vote of the US Senate on June 24th 2015, which, approving the fast-track, conferred full mandate to Obama with regard to the TPP and TTIP negotiations. On this point, see also the article of J. WEISMAN, *Trade Authority Bill wins final approval in Senate*, in *"New York Times"*, June 24th 2015. Anyway, up to the present moment, the institutional channels have not fixed a deadline for the end of negotiations yet, even though the participants announced during a joint press conference held on October 5th 2015 to have reach an agreement.

98 The US presidential election is scheduled for November 8th 2016, but they will be preceded by a long election campaign. Among the most favorite candidates for the final win, it appears particularly surprising the Hillary Clinton's position on TPP, externalized through an interview to PBS on October 7th 2015, where the former First Lady declared not to support the conclusion of such an agreement; even more considering that, for what concerns instead the TTIP, except for the idea of an ISDS body, she has never refused to publicly agree on its contents.

In fact, the transatlantic dialogue between these two huge economic powers will inevitably imply some adjustments among the respective domestic regulations and procedures, but it will primarily establish a higher-level international regulatory system.

And if, on the one hand, this process may be considered, under the European countries' perspective, as an ulterior transfer of sovereignty[99] towards the European Union, on the other hand even within the United States some concerns regarding migration and centralization of powers and competences can be found.

Indeed, talking about the United States, the reasoning has to be laid down on a twofold level: on one side, bringing together peculiarities and stakes of 50 very different States is one of the federal institutions' tasks, which on the international stage are supposed to represent the position of the Republic as a whole; on the other side, at the central level the American congress has a directive and advisory role regarding negotiations, although without directly incisive powers.

Having regard to the first aspect, it is useful for the purpose of this work to highlight the strong differences between some States, including for example Vermont, Washington and Oregon[100], where there is a broad environmental awareness and policies for sustainable consumption are spreading, and other States as Texas, Louisiana and Kentucky where opposite logics often prevail.

---

[99] As will be better explained further, the most correct term in this case is "pooling" of sovereignty.

[100] Basically, the States of New England, which is the northeastern area of United States including Rhode Island, Connecticut, Massachusetts, Vermont, New Hampshire and Maine, have always been characterized by a particular attention for the environment. Such an inclination reflects also on food issues, where organic and local products are preferred over genetically modified food and supermarkets. It is worth to remember that, among all, Vermont was the first American State, followed by Maine and Connecticut, to introduce mandatory labeling for genetically engineering on food.
Anyway, even on the west coast it is possible to find some attempts to protect environment and natural resources similar to those outlined in New England.

Paradigmatic of such a situation is the Federal government's attempt in the matter of food labeling[101], which will be discussed in detail in the fourth chapter, aimed at regulating the topic at a central level in order to avoid producing a patchy regulation.

However, the second one of the highlighted points, namely the influence of the Congress over international negotiations, appears more significant.

In this context, it is by no means pleonastic to refer to Article 1[102] of United States Constitution to explain the mechanism whereby congressional stakes could enter into TTIP: the cited provision constitutes, in fact, the foundation of non-delegation doctrine, that is a general principle behind many legal systems, according to which the law-making powers are exclusively entrusted to Parliament (*rectius*, to Congress).

This concept is nonetheless widely interpreted as including the possibility for the Congress, which indeed holds such powers, to create *ad hoc* bodies, devolving them the practical execution of its task. More, such a power should be considered as implicit in Constitution.[103]

What might appear as a debasement of the constitutional principle is, actually, a right-minded correction to an excessively rigorous interpretation of the basic rule and it rather represents nowadays a usual tool in the hands of lawmakers: it is worth to consider that the existence and the tasks of FDA have their roots in this kind of procedure.[104]

---

[101] H.R.1599 - Safe and Accurate Food Labeling Act of 2015.

[102] Here is the full text of Article 1, Section 1: *"All legislative Powers herein granted shall be vested in a Congress of the United States, which shall consist of a Senate and House of Representatives."*

[103] In this sense, according to the different points of view, it is also used the term delegation doctrine. On this point, copious jurisprudence has been produced; above all, see *J. W. Hampton, Jr. & Co. v. United States, 276 U.S. 394 (1928)* and *Whitman v. American Trucking Associations, Inc., 531 U.S. 457 (2001)*.

[104] Surely, this is one of the main obstacles to the creation of an American food security agency untied to political bodies. This point will be diffusely analyzed within the third chapter.

Regarding to international treaties[105], Article 2[106] of the American Constitution confers to Congress the task of flanking the President as well as approving his work in matter of international agreements. In this view, the Senate may not just reject President's bills, but also propose amendments to the official proposal text to discuss at the negotiating table.

Anyhow, the Congress remains at the same time free to consider the option of getting rid of part of its prerogatives, inserting one or more treaties within the so-called fast-track[107], so resulting in the possibility to only approve or refuse as a whole the President's bill, without amendments and changes.

Exactly the slowness of the dialogue between European Union and United States, together with the above mentioned Obama Administration's need to impart a strong acceleration to such discussions, led in June 2015 the Senate to enact such a kind of regulation even with reference to TTIP and TPP, increasing thus the powers of the President and his negotiators.[108]

---

[105] It is compulsory to remember that in the American legal language the word treaty has a much more specific meaning than the general international's one: in fact, Article 1, Section 10 of US Constitution distinguishes between treaties, whose closing is prohibited to the States, and agreements, which can be adhered by the States after the consent of Congress. Moreover, treaties generally require a qualified majority approval consisting in two thirds of the Senate, whereas for the agreements it is sufficient the simple majority.

[106] An excerpt of Article 2, Section 2 is recalled: "*The President exercises the powers in the Advice and Consent Clause with the advice and consent of the Senate. He shall have Power, by and with the Advice and Consent of the Senate, to make Treaties, provided two thirds of the Senators present concur; [...]"*

[107] With more precision, this mechanism, called fast track negotiating authority or trade promotion authority (TPA), is usually adopted by American institutions to boost the internal approval process of negotiating texts. For further information, see C. M. DAVIS, *"Fast-track" or expedited procedures: their purpose, elements, and implications*, Congressional Research Service, July 2003 and J. F. HORNBECK, *Trade promotion authority (TPA): issues, options, and prospects for renewal*, Congressional Research Service, July 2008.

[108] *H.R.2146: Bipartisan Congressional Trade Priorities and Accountability Act of 2015*, June 30th 2015. On the topic it is particularly interesting to highlight that most of the support for President derived (and it could not be otherwise, given the composition of Senate) from the Republican Party, while a large part of Democrats opposed such a centralization of power. For well-informed readers, it has to be noted that, out of five Republicans who voted against the bill, two were pushed also by mere electoral convenience reasons, taking into account that they were (and currently are) candidate in their party's primary election. See also the article

Therefore, at present the United States has opted for a faster and leaner procedure which will certainly foster a stronger progress within the transatlantic dialogue; at the same time, nonetheless, this choice implies an almost blank check of the Congress in favor of President Obama, with a consequent reduction of roles and influences of this body's members.[109]

Ultimately, once reached the overall agreement between the parties on the final text, the American Congress is supposed to vote to ratify it in both the chambers: in this case, in both the Senate and the House of Representatives the majority - a simple majority or a supermajority - shall be reached.[110]

Similarly, within the European Union the formulation process and the final approval of international treaties' contents embrace a multiplicity of bodies, European as well as national.

A lot of pages of analysis and comments could be written - and, actually, have been written - on the progressive sovereignty transfer process from Member States towards what nowadays is the European Union; in this context, it is preferable not to dwell upon the long European integration process, limiting rather to outline the current situation on this matter.

---

of D. PALMER, *US trade vote puts TTIP on faster track*, in *"Politico"*, June 30th 2015.

[109] For a current and deep analysis on the choice to insert TPP and TTIP into the fast-track, see I. F. FERGUSSON, *Trade Promotion Authority (TPA) and the Role of Congress in Trade Policy*, Congressional Research Service, June 15th 2015.

[110] The case of TTIP, given the content of the agreement is not limited only to tariff reduction, can be considered as a congressional-executive agreement, requiring the involvement of the Senate and of the House too. For further information, see I. F. FERGUSSON, *supra*, p. 9 and J. M. SMITH, *Why certain Trade Agreements are approved as Congressional-Executive Agreements rather than Treaties*, Congressional Research Service, April 15th 2013. Particularly, the first of the reports says: *"Under TPA, reciprocal FTAs and multilateral trade agreements that go beyond tariff reductions are treated as congressional-executive agreements, which require the approval of both houses of Congress. Such approval expresses Congress' consent to bind the United States to the commitments of the agreement under international law. This type of agreement is distinguished from both an executive agreement, requiring only presidential action, and a treaty, requiring a two-thirds vote of the Senate. Because reciprocal trade agreements typically result in tariff rate (revenue) changes, the House of Representatives is necessarily involved."*

According to what is foreseen in Article 218[111] TFUE, the ordinary procedure followed by bodies of the Union, in order to conclude international agreements with third countries, requires the Council of the European Union to authorize the opening of negotiations and to define, together with the Commission, the relevant directives. The Council is also invested of the task of appointing, following the Commission's recommendation, the official negotiator, as well as adopting, after the approval of the European Parliament, the agreement's conclusive decision. Nonetheless, the above described ordinary procedure is integrated with the provisions of Article 207[112] on commercial and tariff international agreements: the most prominent difference consists here in the leading role assigned to Commission having regard to the negotiations.

---

[111] An excerpt of the text is reported: *"The Council shall authorise the opening of negotiations, adopt negotiating directives, authorise the signing of agreements and conclude them.*
The Commission, or the High Representative of the Union for Foreign Affairs and Security Policy where the agreement envisaged relates exclusively or principally to the common foreign and security policy, shall submit recommendations to the Council, which shall adopt a decision authorising the opening of negotiations and, depending on the subject of the agreement envisaged, nominating the Union negotiator or the head of the Union's negotiating team.
[...]
Except where agreements relate exclusively to the common foreign and security policy, the Council shall adopt the decision concluding the agreement:
(a) after obtaining the consent of the European Parliament in the following cases:
[...]
(iii) agreements establishing a specific institutional framework by organising cooperation procedures;
(iv) agreements with important budgetary implications for the Union; [...]"

[112] Third subparagraph of Article 207 TFUE foresees:
"Where agreements with one or more third countries or international organisations need to be negotiated and concluded, Article 218 shall apply, subject to the special provisions of this Article.
The Commission shall make recommendations to the Council, which shall authorise it to open the necessary negotiations. The Council and the Commission shall be responsible for ensuring that the agreements negotiated are compatible with internal Union policies and rules.
The Commission shall conduct these negotiations in consultation with a special committee appointed by the Council to assist the Commission in this task and within the framework of such directives as the Council may issue to it. The Commission shall report regularly to the special committee and to the European Parliament on the progress of negotiations."

In the case of TTIP, the Commission is thus committed to supervising the negotiation phase, periodically reporting to the European Parliament[113] and to the Council, which will be finally requested to definitively approve the consolidated text of the agreement.[114]

Nevertheless, considering the very wide ambit of such a treaty, which concerns matters of exclusive competence[115] of the European Union as well as sectors of shared competence[116], even the Member States, through the vote of theirs national parliaments, will be asked to ratify the final agreement.[117]

Therefore, compared to the accelerated and centralized procedure adopted in the United States, the European *iter* is characterized by a greater sharing of responsibilities, what at the same time has allowed the involved bodies to carry out extensive public consultations in each step of the negotiating process.[118]

Moreover, it has to be considered that issues, similar to those faced by the United States in trying to lead each State's sensibilities towards a unique and well-defined position, can be found, often more pronounced, also within the European Union. As a matter of fact, it is not a mystery the

---

[113] In particular, the involvement of European Parliament is here granted by the presence of an appropriate Parliamentary Committee for International Trade (INTA).

[114] See also A. ALEMANNO, *The Transatlantic Trade and Investment Partnership and the Parliamentary dimension of Regulatory Cooperation*, Directorate-General for External Policies of the Union, April 2014.

[115] See Article 3 TFEU.

[116] *Ibid.*, Article 4.

[117] It is, more properly, a so-called mixed agreement, or rather an agreement covering exclusive competence matters, like customs union and common commercial policy, as well as shared competence matters, as environment, agriculture and fisheries. For further information, see P. KOUTRAKOS, *EU International Relations Law*, Bloomsbury Publishing, 2006 e C. HILLION, P. KOUTRAKOS, *Mixed agreements revisited: The EU and its Member States in the world*, Bloomsbury Publishing, 2010.

[118] One instance for all is the on-line based consultation, the fourth one from the beginning of negotiations, promoted by the new European Commissioner for Trade Cecilia Malmström, regarding protection of investments and the hypothesis of an Investor-state dispute settlement body (ISDS). The report released on January 13th 2015 highlighted a diffuse skepticism of public opinion with regard to the latter organism, so that the Commission decided to abandon such a scheme to implement a similar mechanism called Investment Court System.

lack of a "European conscience", due to both the relative young age of the Union and the very different traditions, habits and needs among the Member States.[119]

Given the above, it should be emphasized that the involvement of European and American institutions is not limited just to the negotiation and conclusion phases of TTIP, but it is required even during its more properly "application" stage.[120]

In fact, the presence, within the negotiation texts[121], of a special "horizontal chapter" concerning regulatory cooperation between the parties concurs to lay the foundation for a close collaboration relationship in the future formulation of the relative sectoral policies.

Such a process takes place with a different level of incisiveness on both the legal systems' autonomy, depending on the matters which the respective lawmakers want to intervene on: on one side, the parties agree

---

[119] In this view, it is paradigmatic the example provided by the Geographical Indications, which are protected within the European Union through the PDO/PGI system: compared to countries such as France and Italy which make these symbols a point of strength for the quality of products, on their own representing more than a third of registered denominations, other countries such as Germany and United Kingdom does not seem particularly interested in the indications' system.
It is not just a coincidence that the German Minister for Food and Agriculture Christian Schmidt in January 2015 expressed himself in the following terms, angering many of his European colleagues: *"If we want to seize the opportunity of free trade with the giant American market, we can no longer protect every sausage and every cheese as being a specialty."*

[120] For an interpretation of TTIP as a "living agreement", see ALEMANNO, *The Regulatory Cooperation Chapter of the Transatlantic Trade and Investment Partnership: Institutional Structures and Democratic Consequences*, Journal of International Economic Law, August 28th 2015, p. 10. A pace of the text is here reported: *"Although TTIP falls short of establishing an internal market between the two sides of the Atlantic (i.e. no joint decision-making power is foreseen), it is set to create the conditions for prompting a new awareness in the minds of the respective regulators: that of the extraterritorial impact of their existing and proposed regulations. Indeed, unlike any previous international regulatory cooperation mechanism, TTIP is set to create a permanent mechanism. TTIP will therefore emerge as a 'living agreement' where new areas of cooperation can be identified without the need to re-open the initial international agreement nor to modify each other's institutional frameworks."*

[121] *EU Proposal for a Chapter on Regulatory Cooperation*, as originally published on February 10th 2015, subsequently amended and released on May 4th 2015 and currently available at trade.ec.europa.eu/doclib/docs/2015/april/tradoc_153403.pdf

to adopt good regulatory practices on all the topics covered by TTIP[122], releasing at least once a year a report containing the planned regulatory acts at central level[123] and promoting public consultations on these matters[124]; on the other side, where regulatory acts at central and non-central level concerning such sectors may have a significant impact on trade or investment between the parties[125], there will be a real regulatory cooperation.

Such more stringent kind of collaboration is mainly implemented through two instruments: the designation of the respective official offices responsible for coordinating the exchange of information between the parties[126] and the institution of a Regulatory Cooperation Body (RCB)[127] composed of politicians and other competent representatives[128], committed to ensuring the participation of stakeholders as well as to preparing and releasing an Annual Regulatory Cooperation Programme common to both the parties.

Exactly this second tool, which at first glance may appear as endangering the European and American parliamentary sovereignty, has actually a mere advisory and supervisory role on the cooperation process, considering that every possible legislative vocation is expressly excluded.[129]

Finally, the negotiating texts take also care of indicating the way for an effective management of the eventual issues which may intervene during the application stage of the treaty, discouraging the adoption of dispute

---

[122] Article 3.1, *EU Proposal for a Chapter on Regulatory Cooperation*.

[123] *Ibid.*, Article 5. It has to be considered that, while for the European Union regulatory acts at the central level definitively consist of directives, regulations and delegated or implementing acts, for the United States they are federal statutes, administrative rules and executive orders of federal agencies.

[124] *Ibid.*, Article 6.

[125] *Ibid.*, Article 3.2.

[126] It is the so-called Focal point, as foreseen in Article 8.3, basically analogue to the so-called Contact point foreseen in Article 9, Chapter 26 of CETA.

[127] *Ibid.*, Article 14. A similar body, called instead Regulatory Cooperation Forum (RCF), is foreseen also in Article 6, Chapter 26 of CETA.

[128] *Ibid.*, Article 16.

[129] *Ibid.*, Article 14 letter c).

settlement procedures and endorsing instead a regular monitoring system, directly controlled by political institutions.[130]

Given the above, during the last few months, and primarily after the last negotiation round, the parties have increased their commitment to promoting transparency and public participation in both the current negotiation process of TTIP and the future regulatory cooperation framework.[131]

In fact, working on the mentioned framework, it has been deeply discussed the role and the impact of the chapter on regulatory cooperation.[132] Particularly, the European Union asks to completely exclude the application of the dispute settlement mechanism to any matter related to regulatory cooperation.[133]

It remains to be seen, in further negotiations, what will be the concrete level of enforcement that such *ad hoc* bodies and structures will succeed to provide with.

---

[130] *Ibid.*, general note No 4. It refers to a Joint Ministerial Body.

[131] Such a commitment is particularly encouraged by the European Union, which during the discussions with civil society and stakeholders promoted after having released its proposal had to face the strong criticism of part of the public opinion. For these reasons, the Commission presented a new, revised proposal during the 12th negotiating round. See also the *Introduction to the EU's revised proposal on Regulatory cooperation in TTIP*, released on March 21st 2016.

[132] See *EU Revised Proposal for Chapter on Regulatory Cooperation*, as made public on March 21st 2016. Among the notable provisions, the exclusion of any legal binding to legislate originating from the regulatory cooperation mechanism for the domestic regulators, the voluntary nature of such a cooperation and the assignment of three criteria - political accountability, transparency and effective coordination – to meet when implementing cooperation.

[133] *EU Revised Proposal for Chapter on Regulatory Cooperation*, Article x.9: "*The provisions of dispute settlement under Chapter XX (Dispute Settlement) do not apply to any matter arising under this chapter.*"

CHAPTER TWO

FOOD SAFETY

Within the following chapter the work will deal with themes, cases and issues which should per se deserve a separate discussion, such is the mole of publications, reviews and essays sedimented during the last thirty years.
The differences between the food safety systems as developed within the European Union, on one side, and within the United States, on the other, will be accurately analyzed.
The main stages which have led to outline the two current regulations will be retraced, lingering also on the nature of the key organisms involved into the risk analysis process and on the relevant dissimilarities which some political decisions have concurred to sharpen in the course of time.
In so doing, it will be necessary to take into account the most dynamic and, at the same time, thorny part of a work on global food safety, namely the comparison, which in the pathological dimension degenerates into mere conflict, between the different regulations at stake at the time of their practical application.
As a whole, the combined interpretation of the converging and diverging points of the regulations adopted by each commercial partner will offer some interesting hints to measure and evaluate the progress of the TTIP negotiations and its possible final content.
A brief technical annotation has to be underlined before going further: this chapter is mainly intended to cover those aspects of both the United States and the European Union's policies that deal with the world of food safety. Therefore, it cannot be considered as an exhaustive insight of all

the agriculture-related topics which TTIP may contain in its final formulation, whatever it will be.[134]

In this view, it is worth to mention what the European Union has proposed to the United States during the last negotiation round with reference to the global matter of agriculture.[135]

In fact, negotiators are proposing to create a global chapter on agriculture, including in the same all the provisions which deal with agricultural matters - including a special section on wine and spirits drinks separately considered so far[136] - as well as provisions on non tariff-issues.

Conversely, issues related to geographical indications should constitute, as it will highlighted hereafter, an autonomous and independent chapter.[137]

More, an additional chapter on sanitary and phytosanitary measures will probably see the light in the final talks of the negotiating process.[138]

The following lines do not follow the hypothetical scheme designed by negotiators, trying instead to design the big picture on comparative food safety rules and policies.

1. FROM THE ORIGINS OF FOOD SAFETY TO PRESENT DAYS

The concept of food safety is ageless or, better, it cannot be dated: since the so-called Code of Hammurabi, which still represents one of the first collection of written provisions, going through the Classical Greece and the Roman Empire, coming to the more recent Medieval era, the eating

---

[134] To give a dimension of the impact of TTIP's provisions on the economy of both the United States and the European Union, consider that trade in agricultural products between the parties accounted for some 35 billion dollars in 2015.

[135] The reference goes to two negotiating texts - both released on March 21st 2016 – representing the European Union standing on trade in agriculture, namely the *Guide to the EU's proposal on Agriculture and Geographical Indications (GIs)* and the *Draft Chapter on Agriculture*.

[136] See Chapter 5.3 hereafter.

[137] See Chapter 5. It is not clear at this point where geographical indications of wine products will be considered under TTIP, whether under the Chapter on Agriculture or the Chapter on Geographical Indications.

[138] See Article X.1 of the *Draft Chapter on Agriculture*.

habits of peoples have contributed in coagulating precepts, maxims and rules of various contents regarding food and its production and preservation modalities.[139]

Anyway, notwithstanding the millenary evolution of food law, neither nowadays it is possible to rely on a universal notion of safety, intended as food healthiness, prescinding from the need to take into account standards of risk acceptability.

Hereby it is compulsory to underline, in simpler terms, that the concept of food safety does not correspond - and never will correspond - to the absence of risks related to food consumption; and, moreover, that, established the inexistence of a risk-free system, it is necessary to set a threshold below which the risk related to the consumption of such a food has to be considered, exactly, acceptable.[140]

The point becomes even more problematic considering that, since it is a standard fixed by men, legislatively[141], it results questionable in itself and, as such, differently quantifiable moving through space[142] and time.[143]

Both the European Union and the United States do not except to such a mechanism, so much so that, despite some positive processes of

---

[139] See M. FERRARI, U. IZZO, *supra*, pp. 19-20.

[140] See M. FERRARI, U. IZZO, *supra*, pp. 50-51.

[141] Obviously, on the basis of scientific data which corroborates the adoption of a certain political choice.

[142] In our case, taking the example of one of the many pesticides used by the American farmers, namely Bentazon, it has to be noted that, while the United States applies a tolerance for residues on food variable from 0.02 to 10 ppm (parts per million), within the European Union remains an unique limit of 0.1 mg/kg. For further information and comparisons between the American end European maximum residue levels of pesticides, see Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC, as well as the U.S. Code of Federal Regulations, Title 40, Part 180.

[143] Just to remain on the boundless field of pesticides, the use of Atrazine in cultivation, once allowed, has been banned since 2004 by the European Commission due to the high amount of the substance recorded by the analysis of groundwater. Atrazine that, incidentally, is still widely used by American farmers.

regulatory homogenization[144], many are the sectors of food law which still present dissimilar rules[145] or inspection procedures[146].

Proceeding in an orderly fashion, the next step is to see how food law developed within the United States, recapping the main stages of its evolution.

Even before the birth of the United States as it is known nowadays, in the first half of the seventeenth century, in New England, the first regulations on food-related issues, principally committed to guaranteeing salubrity of foods and to preventing frauds, were settled.[147]

Subsequently the Declaration of Independence of July 4th 1776, still in the territory of the earlier colonies it can be found out the first systematic regulation on food safety, namely the 1785 Massachusetts Food Act.[148]

---

[144] For instance, consider the *EU-US Organic Equivalency Agreement*, Nuremberg, February 15th 2012, which has allowed, since June 1st of same year, to export, sell and label as organic in both the continents those products which have been recognized as such by the European or the American institutions. In this way, the double-certification mechanism, previously required to label as organic the organic products for export, is ceased.

[145] Consider the protection of Geographical Indications among the European Union, as formulated in Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs and the almost inexistence of such a concept within the United States.

[146] Even where the standards are the same, rules could create practical differences within the controls on food safety. The pamphlet released by the European Commission on the myths about TTIP provides the example of the oysters: while in the United States the bacteriological analysis takes place on the water in which the oysters are grown, within the European Union it is performed on the oysters themselves. Nevertheless, most recent scientific studies highlight that both the procedure are equally effective.

[147] Amongst the first documents, we can refer to the regulation on prices and weights of bread, enacted in 1640 by the Massachusetts Bay Colony and accompanied by a specific Assize of Bread six years later, as well as the act on the adulteration of pork meat in 1641. See P. A. CURTIS, *Guide to food laws and regulations*, Blackwell Publishing, 2005, p. 26 e H. W. FARNAM, C. DAY, *Chapters in the History of Social Legislation in the United States to 1860*, The Lawbook Exchange, 1938, p. 107.

[148] Massachusetts Food Act, March 8th 1785. This is the full text:
"An Act Against Selling Unwholesome Provisions
Whereas some evilly disposed persons, from motives of avarice and filthy lucre, have been induced to sell diseased, corrupted, contagious, or unwholesome provisions, to the great nuisance of public health and peace:
Be it therefore enacted by the Senate and House of Representatives, in General Court assembled, and by the authority of the same, That if any person shall sell

The following development of the United States then contributed to increase the volume of the foodstuff trade, making gradually more frequent and necessary the regulatory intervention to fight against unfair commercial practices and to ensure food hygiene and safety as well.[149]

However, a main stage of great prominence for the evolution of the American food law occurred only at the beginning of the twentieth century, when the investigation carried out in a meatpacking industry of Chicago by the journalist Upton Sinclair led to the publication of the report *The Jungle*.[150] The inquiry was a great shock for the public opinion, due to the inhumane conditions faced by workers as well as the unacceptable sanitary standards of the slaughtering process.[151]

---

any such diseased, corrupted, contagious or unwholesome provisions, whether for meat or drink, knowing the same without making it known to the buyer, and being thereof convicted before the Justices of the General Sessions of the Peace, in the county where such offence shall be committed, or the Justices of the Supreme Judicial Court, he shall be punished by fine, imprisonment, standing in the pillory, and binding to the good behaviour, or one or more of these punishments, to be inflicted according to the degree and aggravation of the offence."
For further information, see N. D. FORTIN, *Food Regulation. Law, Science, Policy and Practice,* Wiley, 2009, pp. 4-5.

149 In this view can be read the institution of the famous "Poison Squad" in 1902 by Dr. Harvey Wiley, at that time chief of the Bureau of Chemistry, composed of twelve volunteers who had offered themselves to test the effects of the additives with suspected toxicity. The outcomes of the test aroused a big clamor among the public opinion and contributed to urge for the implementation of a federal regulation.

150 U. SINCLAIR, *The Jungle*, Doubleday, February 26th 1906. We report an excerpt of the text: "*There was never the least attention paid to what was cut up for sausage; there would come all the way back from Europe old sausage that had been rejected, and that was moldy and white - it would be dosed with borax and glycerine, and dumped into the hoppers, and made over again for home consumption. There would be meat that had tumbled out on the floor, in the dirt and sawdust, where workers had tramped and spit uncounted billions of consumption germs. There would be meat stored in great piles in rooms; and the water from leaky roofs would drip over it, and thousands of rats would race about it. It was too dark in these storage places to see well, but a man could run his hand over these piles and sweep off handfuls of the dung of rats. These rats were nuisances, and the packers would put poison bread out for them, they would die, and then rats, bread and meat would go into the hoppers together."*

151 See N. FORTIN, *supra*, p. 6, P. A. CURTIS, *supra*, pp. 29-30 e C. I. P. THOMAS, *In food we trust. The politics of purity in American food regulation*, University of Nebraska Press, 2014, pp. 18-19. We quote also a pace of P. J. HILTS, *Protecting America's Health: The FDA, Business, and One Hundred Years of Regulation*, Alfred. A. Knopf, 2003 on the effect produced in the reader by the description of Sinclair: "*Particularly disturbing were the accounts of workers, sick with tuberculosis, spitting onto the floor, then dragging butchered meat across it.*

The almost insupportable pressures in favor of a radical federal regulation forced thus in 1906 the President Theodore Roosevelt to promulgate two important acts, the Pure Food and Drug Act[152] and the Meat Inspection Act[153], which marked the dawn of a modern era for the American food law.

Then, after a reorganization of the government bodies which created the Food and Drug Administration (FDA)[154], that is still the most relevant American agency on food law together with the USDA, the sulfanilamide scandal[155] on one side and the pressing campaign bore by the FDA itself for the reformation of food safety provisions[156] on the other induced the Congress to approve in 1938 the Food, Drug and Cosmetic Act (FDCA)[157].

There were tales of meat in storage rooms, rotting and covered with rat droppings, which was then made into sausage, detritus and all. There were even tales of workers who had fallen into the great acidic lard vat and become, after their bones had been finished out, a part of 'Durham's Pure Leaf Lard'".

[152] *Pure Food and Drug Act. An act for preventing the manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, and liquors, and for regulating traffic therein, and for other purposes*, June 30th 1906.

[153] *Federal Meat Inspection Act*, June 30th 1906. The text has been emended by the *Wholesome Meat Act* of December 15th 1967.

[154] In July 1927 the previous Bureau of Chemistry, branch of the United States Department of Agriculture (USDA), was dismantled to institute the Food, Drug and Insecticide Administration (FDIA) under the control of the United States Department of Health and Human Services (HHS). Three years later the FDIA changed its name into Food and Drug Administration (FDA).

[155] In 1937 a pharmaceutical company released a medicine for sore throat called sulfanilamide, consisting of a mixture of antibiotics and diethylene glycol, without carrying out a safety test, because it was not required. The drug caused the death of at least 107 people, mostly children. See FORTIN, *supra*, p. 6, P. A. CURTIS, *supra*, p. 31 e P.J. HILTS, *supra*, p. 89-92.

[156] See R. D. LAMB, *American chamber of horrors: the truth about food and drugs*, Farrar & Rinehart, 1936. The author, at the time chief executive officer of FDA, profited of the book to denounce the backwardness of American food law respect to the consumers' needs.

[157] *Federal Food, Drug and Cosmetic Act. An act to prohibit the movement in interstate commerce of adulterated and misbranded food, drugs, devices, and cosmetics, and for other purposes*, June 25th 1938. The act is still applicable, although it has been repeatedly amended over time.

In the years following, except for few sectoral provisions on the subject of chemical additives[158] and food labeling[159], there have not been momentous innovations until the beginning of the new millennium, when, in response to the tragic events of September 11th 2001, the Congress implemented a legislation aimed at opposing biological terrorism, namely the so-called Bioterrorism Act[160].

Coming to present days, in 2011 the Obama administration enacted the Food Safety Modernization Act (FSMA)[161], an important global reform concerning the subjects overseen by FDA which introduced remarkable changes with regard to the safety inspection procedures and the requirements to import foodstuff.

As regards instead the development of food law within the European Union, for brevity only the regulations emanated at the European level will be considered here, although it is well-known that the safety of foods has been regulated by the individual Member States since centuries ago[162],

---

158 *Food Additives Amendment. An act to protect the public health by amending the Federal Food, Drug, and Cosmetic Act to prohibit the use in food of additives which have not been adequately tested to establish their safety*, September 6th 1958 and *Color Additive Amendment. An act to protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on foods, drugs, and cosmetics, in accordance with regulations prescribing the conditions (including maximum tolerances) under which such additives may be safely used*, July 12th 1960.

159 *Nutrition Labeling and Education Act. An act to amend the Federal Food, Drug, and Cosmetic Act to prescribe nutrition labeling for foods, and for other purposes*, November 8th 1990.

160 *Public Health Security and Bioterrorism Preparedness Response Act. An act to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies*, June 12th 2002.

161 *FDA Food Safety Modernization Act. An act to amend the Federal Food, Drug, and Cosmetic Act with respect to the safety of the food supply*, January 4th 2011. See also C. MIELING, *Are you really going to eat that? Product tracing, the Food Safety Modernization Act, and the promise of RFID*, Illinois Journal of Law, Technology, and Policy, May 2014.

162 An ancient example is the *Reinheitsgebot*, the Purity law enacted by William IV in Bavaria in 1516 and then diffused in the whole Germany during years, which set prices and ingredients of beer. This regulation survived until 1987, when the Court of Justice of the European Union in case C-178/84 considered it inconsistent with Article 30 of EEC Treaty (now Article 34 TFUE). See also M. FERRARI, U. IZZO, *supra*, p. 20 e B. VAN DER MUELEN, *EU Food Law Handbook*, Wageningen Academic Publishers, 2014, pp. 206-207.

when the political geography of the Old World was very different from the current one.

Even though the history of the European Union[163] as a legal system is much more recent than the American one, it is not correct to think that the European food law has experienced with a lower evolution, without relevant changes in the policies established by the responsible bodies.

From this point of view, it has to be considered that, since 1957, i.e. from the birth of the European Economic Community (EEC), the attention reserved to food law issues has been mostly influenced by the political desire to create a common market for the agricultural products, so the aspect more properly related to food safety has been resting in background for long time within the European regulatory landscape.

The development of the European internal market[164] as currently known had then to reckon not just with the succession of regulations of different rank and with the revision of the fundamental acts, but also with a thriving jurisprudence of the Court of Justice of the European Union (CJEU)[165], which repeatedly ruled on the compatibility of some national measures with the freedom of movement for goods as provided by the founding treaties.[166]

In this view, an important turning point is certainly represented by the decision of the *Cassis de Dijon* case[167], where for the first time ever it was explained the mutual recognition principle, which does not allow the

---

[163] The reference to the European Union has to be intended here as the current stage of an integration process started in 1957 with the Treaty of Rome which instituted the European Economic Community (EEC) and still under evolution.

[164] The concept of "internal market" has to be considered as the prosecution of the project of European common market.

[165] Contemplated within the Treaties of Rome in 1957 and at first named Court of Justice of the European Communities (CJEC), the Court was then renamed Court of Justice of the European Union (CJEU) in occasion of the Treaty of Lisbon in 2009.

[166] The free movement of goods is, together with the services, the capital and the people ones, one of the four fundamental freedoms within the European Union and has its legal basis in the arts. 26, 28-37 TFUE.

[167] Court of Justice of the European Communities, C-120/78, February 20th 1979. See also M. FERRARI, U.IZZO, *supra*, p. 25-26 e B. VAN DER MEULEN, *supra*, p. 203-204.

Member Countries to prohibit to import and sell within their territories a product which has been regularly produced within another Member Country.[168]

The principle enounced in the decision could be already perceived between the lines of the precedent statement of the Court in the *Dassonville* case[169] five years before, where nevertheless the judges confined themselves to deny the lawfulness of measures that produce an effect equivalent to a quantitative import restriction. Note that in both the decisions the subject matter was represented by foodstuff: first a whisky, then a liqueur.

At the same time, a change of perspective took place also with regard to the lawmaker's approach to the food issues, moving from sectoral provisions related to individual types of food[170] to more far-reaching systematical regulations[171]. The creation of autonomous and self-contained law systems for each variety of food could have led to a juniper bush of European regulation and have undermined the basic assumptions for an efficient functioning of the single market.

---

[168] We quote an important pace of the decision: "*There is therefore 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; the sale of such products may not be subject to a legal prohibition on the marketing of beverages with an alcohol content lower than the limit set by the national rules.*"

[169] Court of Justice of the European Communities, C-8/74, July 11th 1974. See also M. FERRARI, U.IZZO, *supra,* p. 25 e B. VAN DER MEULEN, *supra,* p. 203.

[170] There is plenty of examples of regulations on individual foods: Council Directive 2001/110/EC of 20 December 2001 relating to honey; 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, now replaced by Directive 2000/36/EC of the European Parliament and of the Council of 23 June 2000 relating to cocoa and chocolate products intended for human consumption.

[171] Paradigmatical examples, the Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs, then replaced by the 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; the Council Directive 93/43/EEC of 14 June 1993 on the hygiene of foodstuffs then encompassed by the Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs.

The emersion of the importance of such a regulation on the salubrity of foods occurred however only after the scandal of the so-called "mad cow"[172], in the earlier '90s. The huge stir aroused by the death of many people, together with the great cohesion and perseverance shown by the European Parliament in trying to avoid the recurrence of such a disaster and, at the same time, to bring to light the political liabilities of the dram[173], led the food safety issues at the top of the list of the European agenda.

Readily, the Commission released a Green paper on food safety[174], which was unfortunately followed by two events of impact on the European system, although different in nature: on one side, the corruption scandal which forced to resign the Commission chaired by Jacques Santer[175]; on the other side, the alert of the dioxins found in Belgian poultry[176], rapidly dammed by the action of the European institutions.

---

[172] We refer to the Bovine Spongiform Encephalopathy (BSE), a chronic neurodegenerative disease transmissible to human identified for the first time in cattle from the United Kingdom. Clinical studies confirmed the relation between BSE and a new variant of the Creutzfeld-Jakob Disease (vCJD), which lead people to a form of progressive fatal dementia.

[173] The European Parliament instituted a Temporary Enquiry Committee on BSE, chaired by Manuel Medina Ortega, which carried out an accurate investigation then resulted in a report on February 7th 1997. The report criticized British institutions for having hidden the problem as well as the Commission for not having guaranteed proper safety controls, preferring to protect the companies' business stakes instead of the health of the European consumers. An excerpt of the text: *"[Commission] has given priority to the management of the market, as opposed to the possible human health risks existing in the light of the numerous scientific uncertainties concerning the possible effects of BSE on humans, and has neglected the principle of preventive action. There is a considerable body of material confirming this attitude."* See also B. VAN DER MUELEN, *supra*, pp. 210-212.

[174] The general principles of food law in the European Union - Commission Green Paper, April 30th 1997.

[175] The scandal involved mostly the French commissioner Edith Cresson, who nevertheless denied to resign individually and forced the Commission, then replaced by the Prodi Commission, to a mass resignation. Commissioner Mario Monti commented in an interview: *"This Commission has collectively resigned not because of collective responsibility but because certain members of it preferred not to take their own individual responsibilities."*

[176] In the first half of 1999 in Belgium were found high levels of Polychlorinated biphenyl (PCB), an organic compound with a structure very similar to the dioxins' one (from which the case took the name). Although the scientific studies on the toxicity deriving from the PCB contamination led to different results depending on

In 2000, the new European Commission led by Romano Prodi released the famous White Paper on food safety[177], which set the stage for the institution of a European Food Authority[178] and identified the necessary steps to implement the standards and the controls existing at the time, in view of a real overall reset of the European food safety.

The great acceleration imparted by this series of events had the merit of contributing to provide the European Union with an advanced system of food safety: just think of the several regulations enacted in the years following, first of all the aforementioned reg. 178/2002, which can be considered the cornerstone of the European food safety and which instituted the awaited European Food Safety Authority.

The new millennium has thus witnessed to a flourishing European food legislation: just to mention the most important regulations, it has to be remembered also the so-called 2004 Hygiene package[179], reg. 1924/2006 on nutrition and health claims[180], as well as reg. 1169/2011 on information

---

the type of risk assessment method, the scandal produced anyway a huge clamor and a loss estimated around the 625 million euro.

[177] White Paper on food safety, Brussels, January 12th 2000. Note that usually the Commission uses the Green paper as a way to externalize its intentions and the areas on which it wants to create public discussion, while the White paper is commonly used to establish real political intents.

[178] The original denomination did not include the word safety, which was then inserted at the suggestion of Philip Whitehead MEP. On this point, see A. ALEMANNO, S. GABBI, *Foundations of EU Food Law and Policy. Ten years of the European Food Safety Authority*, Ashgate, 2014, p. 17.

[179] The Hygiene package is composed of three regulations: Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs, Regulation (EC) n. 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for on the hygiene of foodstuffs and Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption.

[180] Regulation (EC) n. 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods.

to consumers[181] and the succession of regulations protecting the geographical indications[182].

Concluded this brief but compulsory excursus through the steps which have concurred to build the European and American food safety systems, the following step is to analyze the bodies which have the task to make them work properly.

2. THE FOOD SAFETY AGENCIES: EFSA AND FDA

The governance system of American food safety surely has not the merit of being easily understandable *prima facie*, such is complicated the ramification of responsibilities within the various federal agencies.

For convenience of presentation, the most of the analysis will be focused on the functioning of FDA, which however processes around 80% of at-home American food spending.

Anyway, the United States counts as many as 15 agencies which concur, in different ways, in checking the salubrity of foodstuffs: in addition to the above cited FDA, which has the lion's share of the matter, a significant position is also occupied by the US Department of Agriculture (USDA), which through its Food Safety and Inspection Service (FSIS)[183] is principally committed to guaranteeing the safety of meat, eggs, poultry and related products, as well as their correct labeling and packaging.[184]

---

[181] Regulation (EU) n. 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers.

[182] It is a succession of regulations started with the Council Regulation (EEC) No 2081/92 of 14 July 1992 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs and resulted in the recent Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs.

[183] FSIS was instituted on March 14th 1977 as an agency of the United States Department of Agriculture.

[184] See also N. D. FORTIN, *supra,* p. 25.

Nonetheless, the FSIS has not such incisive powers, especially with regard to those cases of adulterated products recalls, which in fact remain currently a voluntary choice of the producers; at the same time, it can count on a budget and a workforce more consistent than the FDA's one, despite a definitely inferior ambit of products, which represent approximately 20% of foodstuffs on the market.[185]

Hereafter, the summary table used for the US Congress meetings in the year 2014 compares and highlights the main differences between the FDA's organization and function and the FSIS' ones.

Basically, FSIS directly inspects poultry and meat only in those cases where the supply chain involves more than one American State, while where the product remains always in the same State the controls are performed by state inspectors.

[185] In this view, see the table above: compared to the approximated 1.15 billion dollars annual budget and to a more than 9000 people staff of FSIS, the FDA has the residual control over the products not processed by the FSIS, but it can count on a budget for the food sector which amounts to around 880 million dollars and on a total of 3500 workers, just little more than a third of the FSIS' ones. However, it has to be considered that the FDA funding is intended to gradually increase, while the FSIS funding trend is decreasing. For further information, see R. JOHNSON, *The Federal Food Safety System: A Primer*, Congressional research service, January 17th 2014.

Activity	Food Safety and Inspection Service	Food and Drug Administration (Foods Program only)
Foods Regulated	Major types of domestic and imported meat and poultry and their products; catfish products; processed (dried, frozen, liquid) egg products (20% of at-home U.S. food spending)	All other domestic and imported foods, also animal drugs and feeds including those used in food-producing animals (80% of at-home U.S. food spending)
Funding (FY2012)	Appropriated: $1.004 billion for FY2012. Expected user fees are estimated to include another $150 million. Including authorized fees, total available funding is estimated at about $1.154 billion.	Appropriated: $866.1 million for FDA's Foods Program, not including funding from expected user fees. Expected user fees are estimated to include another $16 million. Including authorized fees, total available funding is estimated at about $882.7 million.
Staff (2012)	9,400 FTEs	3,500 FTEs
Domestic facilities	6,300 slaughter and/or processing establishments	68,000 subject to inspection
Labeling	Review and preapproval required for all labels	All foods must adhere to food labeling requirements such as statement of identity, declaration of net contents, nutrition labeling; labels cannot be false or misleading.
Required inspection frequency	Slaughter plants: all times of operation; processing plants: at least once daily	FSMA requires increased inspection rates for any registered facility, particularly those identified as "high-risk." Domestic high-risk facilities are to be inspected not less than once in the five-year period after enactment, and not less than once every three years thereafter. Domestic non-high-risk facilities are to be inspected not less than once in the seven-year period after enactment, and not less than once every five years thereafter.
Imports	Specified products only from countries where FSIS has determined "equivalence" of foreign safety system, with annual verification; imports exempt from prior notice but subject to reinspection at 150 import establishments (est. 10% reinspected)	Prior to FSMA, food safety system equivalence was not determined beforehand; reliance on inspections was at 300 ports (est. 1% of notified entries inspected). FSMA provides for tighter controls and use certification or verification systems for imported foods (to be determined by FDA rulemaking). At least 600 foreign facilities must be inspected the year following enactment, and in each of the subsequent five years the number of foreign facilities inspected is to double.
Recall Authority	No authority to mandate recalls; relies on voluntary efforts	Prior to FSMA, FDA had no authority to mandate recalls (except infant formula). FSMA §206 provides for mandatory recall authority where there is a reasonable probability that a food is adulterated or misbranded, and its use or exposure to it will cause serious adverse health consequences or death. Civil/criminal penalties apply for failure to comply with a recall order.

From this point of view, it has to be mentioned a very important program coordinated by FSIS, namely the State Meat and Poultry Inspections (MPI)[186], which requires the participant States to adopt safety standards at least equal to those contemplated by the above mentioned Federal Meat Inspection Act (FMIA) and by the Poultry Products Inspection Act

[186] For further information, see P. A. CURTIS, *supra*, p. 45-47.

(PPIA)[187]; nevertheless, the States which currently participate in such a program are just 27, as the reader can easily see from the table below.[188]

Listing of Participating States	
State	Meat and/or Poultry Programs
Alabama	Meat & Poultry
Arizona	Meat & Poultry
Delaware	Meat & Poultry
Georgia	Meat Only
Illinois	Meat & Poultry
Indiana	Meat & Poultry
Iowa	Meat & Poultry
Kansas	Meat & Poultry
Louisiana	Meat & Poultry
Maine	Meat & Poultry
Minnesota	Meat & Poultry
Mississippi	Meat & Poultry
Missouri	Meat & Poultry
Montana	Meat & Poultry
North Carolina	Meat & Poultry
North Dakota	Meat & Poultry
Ohio	Meat & Poultry
Oklahoma	Meat & Poultry
South Carolina	Meat & Poultry
South Dakota	Meat Only
Texas	Meat & Poultry
Utah	Meat & Poultry
Vermont	Meat & Poultry
Virginia	Meat & Poultry
West Virginia	Meat & Poultry
Wisconsin	Meat & Poultry
Wyoming	Meat & Poultry

Around 15 other federal agencies and a myriad of State and local bodies complete then the American big picture of food controls: particularly relevant, it is mandatory to mention the Centers for Disease Control and Prevention (CDC)[189], which represents the most important organism to control and monitor public health and which has the task to analyze the cases of foodborne diseases, as well as the U.S. Environmental Protection

---

[187] *Poultry Products Inspection Act. An act to provide for the compulsory inspection by the United States Department of Agriculture of poultry and poultry products,* August 28th 1957.

[188] *States Operating their Own MPI Programs - USDA Food Safety and Inspection Service, March 23rd 2015.*

[189] *Centers for Disease Control and Prevention (CDC),* July 1st 1946. The centers report to the *Department of Health and Human Services (HHS).*

Agency (EPA)[190], which is committed to protecting the American environment dealing with pesticides and water analysis and, at last, the National Marine Fisheries Service (NMFS)[191], which operates in the field of fishing and seafood products.

It is time now for a specific focus on what may be considered as the most important American agency in the matter of food safety, namely the FDA, which deals with food products, cosmetics and drugs. The following lines will relate only to the first of these three sectors.

The apical position of the FDA organization consists in its Commissioner, who reports to the HHS Secretary[192]: the CDC and the National Institutes of Health are, as the FDA, included in the competence of such Department and, more, they receive the largest part of the funding. It has to be noted that FDA definitively derives its powers through a process which is not independent by the government bodies, and the same is, in an even more pronounced way, for the case of FSIS.[193]

The Code of Federal Regulation (CFR)[194] recollects the criteria adopted by FDA performing its tasks and, since it is a collection of the main federal regulations, it is updated annually; besides, with regard to its scope *ratione materiae*, it can be identified residually with respect to the FSIS' one, except for some particular foods or processes, and it is described in the recent FSMA.

---

[190] *United States Environmental Protection Agency, December 2nd 1970.*

[191] *National Marine Fisheries Service (NMFS),* February 9th 1871. The agency is part of the *National Oceanic and Atmospheric Administration (NAOO),* which operates within the *Department of Commerce (DOC).*

[192] See F. R. PARKER, *FDA Administrative Enforcement Manual*, Taylor and Francis, 2005, pp. 2-12.

[193] The FDA and the FSIS as well are in fact controlled by the government, although related to different Departments. Moreover, the FDA Commissioner is nominated directly by the President of the United States, with the consensus of the Senate.

[194] *Code of Federal Regulation, Title 21 - Food and Drugs.*

Furthermore, the FSMA provides FDA with a power requested by the agency itself several times, namely the authority to issue mandatory recalls concerning adulterated or unsafe products.[195]

At the same time, the reform has instituted a series of mandatory inspective acts[196] and production safety standards[197] which, together with the pilot projects whose implementation is delegated directly to the FDA[198], enable to prevent and, in the worst cases, limit the food contamination and the sales of unhealthy and adulterated food.

Certainly, the FDA can nowadays count on an advanced regulatory framework and on authoritative powers which are much more pervasive than it was in the past, even in the recent one.[199]

That becomes more and more evident considering the regulatory innovations on import procedures. In fact, the provisions of the FSMA extend beyond the borders of the United States[200], thanks to the mechanism established by two federal programs, namely the Foreign Supplier Verification Program (FSVP)[201], which requires that importers perform some risk-based activities to verify that imported food has been produced according to the American safety standards, and the Third Party

---

[195] The recall authoritative powers of FDA are used after the refusal of the producer to compel with a voluntary recall suggested by the agency itself, as disposed in Section 206 FSMA, titled "Mandatory Recall Authority".

[196] See Sections 101, 103, 201, 306, Title 21 FSMA.

[197] See Sections 104 and 105, Title 21 FSMA.

[198] See Section 204, Title 21 FSMA. To go deeper on the topic, see C. MIELING, *supra*, pp. 262-263.

[199] Just think that, before the enactment of the FSMA, the so-called Bioterrorism Act and the subsequent 2007 Food and Drug Administration Amendments Act (FDAAA) as well contemplated a traceability system based on the "one-up/one-down" mechanism, which did not take into account neither the numerous transformation which a certain foodstuff could be subjected within the same factory, nor the possible length of the supply chain. See Title 21 of the U.S. Code, Section 350f(d).

[200] See K. HARDEE, *Insuring the Safety of Foreign Foods*, in "*Food Safety Magazine*", February 23rd 2016, in particular where the author states that "*[…] the goal is that any human or animal food, or their ingredients, which are imported into the U.S. must be produced under the same safety standards as food that is produced in this country.*"

[201] *Foreign Supplier Verification Programs for Importers of Food for Humans and Animals*, November 27th 2015.

Accreditation Rules[202], which establishes a voluntary program for the accreditation of auditors to certificate foreign facilities and the food they produce.

Nevertheless, watching at the big picture of the American food safety system, there is an increasing need to deeply reorganize the organizational structure of the various bodies involved in the field, in order to bring to unity such a complicated and often muddler system.[203]

Among the tasks of such a reformation, it would be appropriate to put on top of the list the concentration of safety responsibilities for all sorts of foods underneath a unique body, possibly independent from political influences, in order to avoid cases of overlap or, worse, vacuum of competence.[204]

The table utilized by the American Congress and reported hereafter can give the proof of the current situation in matter of division of powers between the American federal bodies.

---

[202] *Accreditation of Third-Party Certification Bodies To Conduct Food Safety Audits and To Issue Certifications*, November 27th 2015.

[203] See C. I. P. THOMAS, *supra*, pp. 29-32.

[204] Think of the Salmonellosis outbreaks occurred in the few past years in the United States due to the presence of Salmonella within some lots of eggs: in such a case, the safety controls require to involve the FSIS as well as the FDA, because the first one is appointed to the general inspection of eggs, while in case of shelled eggs the responsibility falls on FDA. See the article of G. GOETZ, *Who Inspects What? A Food Safety Scramble*, in *"Food safety news"*, December 16th 2010, available at www.foodsafetynews.com/2010/12/who-inspects-what-a-food-safety-scramble.

Comparison of Selected Agency Responsibilities for Food Safety and Quality

Agency	Responsibility
Food and Drug Administration (FDA)	• Food (but not meat)
	• Dietary supplements
	• Bottled water
	• Seafood
	• Wild game ("exotic" meat)
	• Eggs in the shell
U.S. Department of Agriculture (USDA)	• Grading of raw fruit and vegetables
	• Meat and Poultry
	• Eggs, processing and grading
	• Certifying organic production
National Oceanic and Atmospheric Administration	• Grading of fish and seafood
Environmental Protection Agency (EPA)	• Drinking water
	• Pesticide residues
Customs and Border Protection (CBP)	• Front-line enforcement and referral
Department of Justice (DOJ)	• Law enforcement
Federal Trade Commission (FTC)	• Advertising
Alcohol and Tobacco Tax and Trade Bureau (TTB)	• Alcohol

Source: CRS, as adapted by N. D. Fortin, *Introduction to Food Regulation in the United States*, Part I, May 2008.

Moving instead to the European side, it can be easily perceived the different mindset and organization in the field of food safety: it principally consists in separating the risk assessment phase, which is exclusively administrated by EFSA, from the subsequent risk management one, which is instead carried out by the European political institutions, namely by the European Commission.[205]

Moreover, it has hereby to be underlined an ulterior split within the risk analysis process, in the sense that the risk communication stage[206] is separately considered and it is implemented thanks to the synergy of different subjects: Commission, EFSA, state authorities[207] and producers

[205] It goes without saying that the Commission is assisted in this task by the European Parliament and the Council, as well as the national administrative authorities.

[206] This stage, which may and should take place even simultaneously with the risk assessment and risk management phases, consists in conveying information to stakeholders and it is expressly considered in Article 3.13 of reg. 178/2002. See also M. FERRARI, U. IZZO, *supra*, pp. 72-74.

[207] Here it is referred to the administrative bodies of each individual member country, whose identification is indeed delegated to respective national provisions, which

and consumers associations as well participate in such a process contributing to the circulation of information on food safety.[208]

Looking at the United States, such a distinction cannot be perceived[209], but this feature does not always coincide with a lower level of consumers' awareness[210]: nevertheless, it seems there undeniable that public information has basically less prominence and it is not usually perceived, despite some exception[211], as a right of the consumer to know what he or she is eating.

One of the instruments used to spread and sharpen information within the European Union is the Rapid Alert System for Food and Feed (RASFF)[212], a transparent system[213] which consents to recollect and catalogue all the reports originated in the European Union Member Countries in order to eventually adopt the appropriate safety measures without loss of time.

---

have the task of collaborating with the European institutions to guarantee food safety. See also B. VAN DER MUELEN, *supra*, pp.224-225.

208 To be more precise, it is the EFSA as independent authority the principal body committed to handling the risk communication stage, but in doing these it is supported by political institutions of the European Union and by the single operators within the supply chain.

209 As a matter of fact, it is the FDA or the USDA themselves the agencies which provide for public opinion with information regarding food safety issues.

210 The American regulation on nutrition information, the so-called nutrition facts, is indeed really advanced. The European Union proceeded to align with such standards enacting reg. 1169/2011. See also M. FERRARI, U. IZZO, *supra*, pp. 140-141.

211 For instance, it is useful to think about the increasing pressure applied by public opinion, especially among some of the States of New England, which are particularly sensitive to environmental topics, for a regulation introducing mandatory labeling for genetically modified components.

212 RASFF was established in 1979 under Article 8 and Annex of Council Directive 92/59/EEC of 29 June 1992 on general product safety, which devolved to Commission the task of providing with the implementation of a system for rapidly exchanging food-related information among member countries. Chapter IV of reg. 178/2002 then regulated on its functioning under the new organizational structure of the European food safety system, including into RASFF also feeds, before excluded.

213 Citizens of the European Union can consult RASSF accessing to the dedicate web portal; nonetheless, not all information collected in the system are available for public.

It is evident that such an attention to the risk analysis process finds its reasons among historical events which deeply influenced the European institutions' evolution and certainly concurred to model its current arrangement.

Admittedly, as previously mentioned, the BSE crisis *in primis*, together with other emergency situations, concurred in the emersion of the necessity of separating the scientific evaluation phase from the risk management's one. More, reg. 178/2002 strongly marked the distinction between the phases, assigning the first one to a different and independent body than the Commission[214], namely the EFSA.[215]

Coming to the organizational structure of EFSA[216], it is composed of a Management Board, which comprises a representative of the Commission and fourteen experts appointed by the Council of the European Union after the consultancy of the European Parliament, on the basis of a list prepared by the Commission, an Executive Director with the relative staff, an Advisory Forum and a Scientific Committee flanked by sectoral scientific panels.[217]

As the Management Board is committed to predisposing the annual and multi-annual work programmes as well as to appoint the Executive Director after a public selection procedure, the latter takes care of the correct functioning of the Authority, acting as its legal representative and chairing the Advisory Forum.

The Advisory Forum represents indeed the link between the EFSA and the food safety authorities of each Member Country of the Union, as well as the Norwegian, Icelandic and Swiss ones: its mission is to facilitate

---

[214] It has to be noted that the Commission had a primary role on the mismanagement of "mad cow" crisis. Reducing its powers with regard to sanitary field certainly has concurred to stem the collapse of European citizens' confidence in institutions.

[215] See Chapter III of reg. 178/2002, entirely dedicated to EFSA.

[216] See Article 24 of reg. 178/2002.

[217] See table in the following page for further information on EFSA's structure. It can be easily found on the official portal of the Authority. See also A. ALEMANNO, S. GABBI, *supra*, pp. 48-62.

cooperation among European and national bodies and it is therefore composed of one representative per involved State.[218]

With regard, instead, to the technical aspect of the foodstuffs salubrity, they are processed by the specific panels of experts[219], assisted with coordination functions by the Scientific Committee, which is composed of the sectoral panels' presidents plus six ulterior experts.[220]

Members of the Scientific Committee as well as members of the various panels are appointed after public selection procedures which certify their independence and their skills and expertise.

For the purpose of this work, particularly interesting is Article 30 of reg. 178/2002, which deals with the resolution of problems due to divergence between the scientific opinions provided by EFSA[221] and those provided by other European or national bodies, requiring the parties, in case of controversial scientific issues, to draft a public joint document identifying the uncertain points.[222]

Such a procedure is very prominent considering its relations to the risk management functions attributed to the Commission and to the content of Article 7 of the above mentioned regulation: in fact, on the basis of the

---

[218] *Ibid.*, Article 27.

[219] Currently they are 10: Additives and products or substances used in animal feed (FEEDAP), Animal health and welfare (AHAW), Biological hazards (BIOHAZ), Contaminants in the food chain (CONTAM), Dietetic products, nutrition and allergies (NDA), Food additives and nutrient sources added to food (ANS), Food contact materials, enzymes, flavourings and processing aids (CEF), Genetically modified organisms (GMO), Plant health (PLH), Plant protection products and their residues (PPR).
At the beginning, most of the work was proceeded by the panel on Food additives, flavourings, processing aids and materials in contact with food (AFC), then split into two separated panels, namely ANS and CEF, by Commission Regulation (EC) No 202/2008 of 4 March 2008 amending Regulation (EC) No 178/2002 of the European Parliament and of the Council as regards the number and names of the Scientific Panels of the European Food Safety Authority.

[220] *Ibid.*, Article 28.

[221] *Ibid.*, Articles 22 and 29.

[222] See also A. ALEMANNO, S. GABBI, *supra*, pp. 20-21.

precautionary principle, the Commission's approach to resolve the impasse may be more cautious than ever.[223]

It will be discuss deeper in the following chapter how tough this collaboration can result in the case of the authorization procedure for releasing in the market genetically modified products.

3. COMPARATIVE FOOD SAFETY: LAW ON THE BOOKS AND LAW IN ACTION

In the following lines some of the friction points between the European and the American regulation on food safety will be analyzed, paying a particular attention to their practical implications and their incidence on the trade relations between these two major economic powers.

Among the trickiest international disputes in the food industry, it seems almost obvious to begin from the quarrel concerning the ban imposed by the European Union - *rectius*, by the European Economic Community - on imports of hormone-treated beef in the late 1980s.

Actually, since 1981 the Council of the European Economic Community enacted a directive[224] aimed to limit, if not to totally impede, the hormone administration to cattle in the European farms[225], prohibiting at the same time imports of meat which did not fulfill the directive's requirements.

---

[223] It is here underlined the role of Commission and EFSA within the risk analysis process: differently from the American model, EFSA is charged just with its first stage, and it works substantially within a "two-tier regulatory framework" or, even better, a "multilevel regulatory framework". See also B. EBERLEIN, E. GRANDE, *Beyond delegation: transnational regulatory regimes and the EU regulatory state*, in "*Journal of European Public Policy*", Routledge, 2005, pp. 98-99 e A. ALEMANNO, S. GABBI, *supra*, pp. 74-90.

[224] Council Directive 81/602/EEC of 31 July 1981 concerning the prohibition of certain substances having a hormonal action and of any substances having a thyrostatic action.

[225] The directive nonetheless foresaw the possibility for member States of authorizing the usage of a series of hormonal substances, otherwise banned, for therapeutic purposes or to improve the reproductive process.

In particular, Articles 5[226] and 8 of the directive requested the Commission to start a scientific study on the consequences for human health related to the consumption of meat treated with estradiol, progesterone, testosterone, trembolone and zeranol for fattening purpose.[227]

The Commission, subsequently the result of the scientific report, after having unsuccessfully proposed the enactment of a directive to allow the controlled use of natural hormones for fattening purpose[228], instead ended up with aligning with the Council's standing, prohibiting the usage of all the five types of hormones (plus the melengestrol acetate).[229]

What is most important to underline with regard to such a ban is first of all its impact on the international trade, taking in fact into account that in the United States as well as in Canada the use of such hormonal substances not only had always been admitted beyond the normal

---

[226] The full text of Article 5 says: *"The Council, acting unanimously on a proposal from the Commission shall take a decision as soon as possible on the administering to farm animals of oestradiol 17/ß, Progesterone, Testosterone, Trenbolone and Zeranol for fattening purposes.*
Pending adoption of this decision, the national regulations in force and the arrangements made by Member States concerning these substances shall continue to apply while complying with the general provisions of the Treaty and without prejudice to measures adopted in accordance with a Community procedure designed for their approximation.
Member States may not authorize the use of new substances during this transitional period."

[227] Estradiol, progesterone, testosterone, trembolone and zeranol are, together with the melengestrol acetate (MGA), the protagonists of the entire dispute between United States and European Union among WTO. The first three hormones are naturally occurring in both the humans and the animals, while the other three are the result of chemical synthetic processes.

[228] The Commission's position was strongly opposed by the European Parliament, which established two Committees of Enquiry on the topic. For further information, see T. E. JOSLING, D. ROBERTS, A. HASSAN, *The Beef-Hormone Dispute and its implications for Trade Policy*, September 1999, pp. 6-9.

[229] See the provisions of Council Directive 85/649/EEC of 31 December 1985 prohibiting the use in livestock farming of certain substances having a hormonal action, subsequently annulled by the European Court of Justice on procedural grounds and reproduced in the Council Directive 88/146/EEC of 7 March 1988 prohibiting the use in livestock farming of certain substances having a hormonal action.

therapeutic use[230], but also was a common habit among all the big livestock feedlots.[231]

Immediately, the United States tried to refer the issue to GATT, alleging that the measures established by the European Economic Community constituted a trade barrier: nevertheless, the procedure then in force for resolving these disputes permitted to any GATT Member State[232] to block such attempts.[233]

Therefore, the United States opted for a series of retaliatory measures starting from 1989, imposing huge duties on a list of products imported from Europe[234], which induced the Commission to ask for the institution of a panel among GATT, option this time refused by the United States.[235]

Taking into account that in the meantime the Uruguay Round negotiation were having place, both the parties tried to restrain the consequences of such a disagreement, preferring instead to work on finding a solution within the international structure at the time under construction, namely the WTO.

---

[230] See instead the example of clenbuterol, suspected as dangerous for human health and for this reason expressly prohibited within the European Union and limited to the therapeutic use as a bronchodilator among the horse feedlots in the United States. On this point, see 21 CFR, Part 520.452.

[231] See also W. A. KERR, J. E. HOBBS, *Consumers, Cows and Carousels: Why the Dispute over Beef Hormones is Far More Important than its Commercial Value*, in *The WTO and the Regulation of International Trade*, Edward Elgar Publishing, 2005 and R. JOHNSON, *The U.S.-EU Beef Hormone Dispute*, Congressional Research Service, January 14th 2015.

[232] Included, in this case, the Commission.

[233] This point has already been under discussion at footnote n. 60. See furthermore C. E. HANRAHAN, *The European Union's Ban on Hormone-Treated Meat*, Congressional Research Service, December 19th 2000.

[234] They were duties of 100% of value on products intended to be imported into the United States, for a total amount of around 93 million dollars. See also M. A. POLLACK, *The Political Economy of the Transatlantic Partnership*, Robert Schuman Centre for Advanced Studies, June 2003, pp. 24-25.

[235] Actually, in order to find a compromise, in February 1989 a task-force was established, composed of representatives of both the powers. This led to an interim agreement which allowed imports of meat from the United States, provided that they were included in a list generated by FSIS which contained the hormone-free certified producers. In exchange, United States undertook to reduce retaliation due to the value of exported products.

The new WTO procedure, in fact, would have no longer allowed a single Member State for blocking the discussion on issues reported from the other States; thus, in 1996 the United States succeeded in obtaining that a WTO panel processed the issue.[236] The year following, the related report brought into light as the ban on hormone beef was inconsistent with the provisions of the SPS agreement.[237]

The European Community so appealed to the Appellate Body, which, despite definitively confirming the point of view of the previous report, accorded to the Community the option of performing a risk assessment on the usage of hormones in beef within a precise deadline.[238]

Nonetheless, when the deadline expired the Community had not carried out a satisfying risk assessment yet[239], nor even agreed on the removal of the challenged measures before further research, only offering the possibility of negotiating compensation mechanism with the United States.[240]

In 2003, the European Community enacted a directive[241] which completely banned the use of estradiol, due to its actual carcinogenic effects

---

[236] *Dispute DS26 European Communities - Measures Concerning Meat and Meat Products (Hormones)*. Also Australia and New Zealand then join the action of United States. Canada instead began a separate but however similar procedure, named as *Dispute DS48 European Communities - Measures Concerning Meat and Meat Products (Hormones)*.

[237] In particular, it was to be considered as a violation of Articles 3.1, 5.1 and 5.5 of SPS agreement, given that the enacted measures were not based on an adequate risk assessment (Article 5.1) or on international scientific standards (Article 3.1). Furthermore, the fact that other substances with similar levels of risk for human health were not likewise forbidden was considered a discriminatory treatment under Article 5.5.

[238] The arbitration panel subsequently fixed the deadline considering 15 months, namely within May 13th 1999.

[239] Actually, the Commission declared to be really close to demonstrating the danger for human of at least one out the six challenged hormones, namely estradiol.

[240] The deadlock was sharpened taking into account that while the United States were disposed to accept compensation only if temporary, waiting for the removal of the imposed ban, the Commission could not undertook in any way such an obligation before having obtained enough satisfying scientific data.

[241] Directive 2003/74/EC of the European Parliament and of the Council of 22 September 2003 amending Council Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists. See whereas n. 6 and 7:

highlighted by the studies, while as regards the other typologies of disputed hormones a provisional ban was maintained, according to the lack of univocal scientific data.[242] At the same time, assuming to have achieved the required scientific evaluation and to legitimately can prohibit the usage of the five suspected hormones under the Article 5.7 of the SPS agreement, the Community called on the WTO to request the cessation of retaliation from the United States.[243]

Thereafter, the dispute has been more and more taking on the characters of a real "trade war", given the almost ascertained incapacity of WTO dispute settlement bodies of finding a satisfying solution to the issue.[244] Thus, currently the United States keeps on pointing the finger at the absence of scientific evidence behind the European Union's choices, while the latter leverages the precautionary principle to sustain the necessity of prohibiting potentially harmful substances.

This pretty known dispute has been followed, more recently, by another one referred to the presence of toxic substances in meat intended for human consumption: this is the rinse of chicken meat with substances other than water, practice which is forbidden in the European Union as well as indisputably admitted in the United States.

"(6) As regards, in particular, the use of oestradiol 17ß, with the aim of promoting growth, the SCVPH assessment is that a substantial body of recent evidence suggests that it has to be considered as a complete carcinogen, as it exerts both tumour-initiating and tumour-promoting effects and that the data currently available do not make it possible to give a quantitative estimate of the risk.
(7) As regards the other five hormones (testosterone, progesterone, trenbolone acetate, zeranol and melengestrol acetate), the SCVPH assessment is that, in spite of the individual toxicological and epidemiological data available, which were taken into account, the current state of knowledge does not make it possible to give a quantitative estimate of the risk to consumers."

[242] In so doing, the European Community quoted the content of Article 5.7 of SPS agreement, which has already been mentioned previously.

[243] *Dispute DS320 United States - Continued Suspension of Obligations in the EC - Hormones Dispute*.

[244] Nothing seems to has changed with the buffer solution represented by the Memorandum of Understanding signed on May 13th 2009 by European Union and United States whereby sales of hormone-free American meat (the so-called High quality beef) within the European territories are permitted in exchange of a remarkable reduction of retaliation.

According to the provisions of the SPS agreement[245], in fact, United States and European Union, once ended the Uruguay Round, went on with a series of bilateral meetings in order to try to reach an agreement on the recognition of mutual veterinary standards on meat and related products; nonetheless, at the expiration of the deadline fixed by the European Union[246], the parties did not succeed in finding a compromise.

Facing the European refusal to accept imports of meat which would not have fulfilled the food safety requirements in force within the Union, United States threatened the imposition of duties on European exports as retaliation: that was enough to persuade both the parties to converge on an Agreement on Veterinary Equivalency the month following.[247]

Moreover, such an agreement embraced a wide variety of meats but totally excluded any recognition on poultry, where in fact a prominent distance between the law systems persisted.[248]

It has to be considered that the American poultry industry was quite established in the European Union at that time. In this sense, after the Uruguay Round, the volume of American poultry exports was expected to grow in the European market, according to the promise of increasing liberalisation.[249]

Such a regulatory distance basically impeded the export of American poultry in the European Union even during the years following, with an

---

[245] See Article 4 of SPS agreement.

[246] Negotiations, which could lasted for maximum three years, ceased unsuccessfully on April 1st 1997.

[247] The Agreement on Veterinary Equivalency, which main points were fixed on April 30th 1997, was nonetheless signed in Brussels two years later, on July 20th 1999.

[248] The problem mainly consisted in the European skepticism about the American food safety parameters: as a matter of fact, while the latters consider the final rinse of carcasses with acid solution (the so-called Pathogen Reduction Treatments) as sufficient for meat salubrity, the European experts underline the need to prevent the presence of pathogen agents in food within all the supply chain.

[249] W. P. ROENIGK, *Transatlantic Trade and Investment Partnership: Achieving the Potential*, October 30th 2013. During the hearing, Roenigk reported that in 1996, i.e. the year before the European ban, the United States exported poultry into the European Union (then counting only 15 States) for 55 million dollars. More, he considered, probably exaggerating a little, that without the ban exports would have increased to 600 million dollars considering all the 28 European countries.

increasing concern of the United States due to the impossibility to access to a substantial sector of poultry market.[250]

The United States so asked the European Union in 2002 for the authorization of four of the principal substance regularly used in poultry washing within the American territories[251], in order to be able to begin exports.[252]

Despite some EFSA opinions[253] excluded possible problems for human health due to the usage of such substances under prescribed conditions[254], the Council decided, six years later, for rejecting this authorization[255],

---

[250] See R. JOHNSON, *U.S.-EU Poultry Dispute on the use of Pathogen Reduction Treatments (PRTs)*, Congressional Research Service, January 14th 2015.

[251] They were namely chlorine dioxide, acidified sodium chlorate, trisodium phosphate and peroxyacids. For concentration levels prescribed in the United States, see 21 CFR, Part 173.

[252] On this point, the Article 3.2 of the above mentioned reg. 853/2004 says: *"Food business operators shall not use any substance other than potable water – or, when Regulation (EC) No 852/2004 or this Regulation permits its use, clean water – to remove surface contamination from products of animal origin, unless use of the substance has been approved in accordance with the procedure referred to in Article 12(2). Food business operators shall also comply with any conditions for use that may be adopted under the same procedure. The use of an approved substance shall not affect the food business operator's duty to comply with the requirements of this Regulation."*

[253] See the Explanatory Memorandum to accompany the EC Proposal for a Council Regulation implementing Regulation (EC) No 853/2004 of the European Parliament and of the Council as regards the use of antimicrobial substances to remove surface contamination from poultry carcasses of October 29th 2008 and the Scientific Opinion of the Panel on Biological Hazards on a request from DG SANCO on the assessment of the possible effect of the four antimicrobial treatment substances on the emergence of antimicrobial resistance, The EFSA Journal 659, April 2nd 2008.

[254] One of the more diffused concerns regarding such typologies of substances is the developing of resistance to antimicrobials.

[255] Council Decision 2009/121/EC of 18 December 2008 rejecting the proposal from the Commission for a Council Regulation implementing Regulation (EC) No 853/2004 of the European Parliament and of the Council as regards the use of antimicrobial substances to remove surface contamination from poultry carcasses. An excerpt of whereas n. 13 is reported: *"The lack of scientific data in relation to hazards related to the use of these substances leads to the application of the precautionary principle as referred to in Article 7 of Regulation (EC) No 178/2002 [...]"*.

unleashing the wrath of the outgoing Bush Administration, which did not hesitate to address the matter to WTO.[256]

Currently, the issue has not been examined yet by the appointed panel[257] - whose composition is still a controversial point between the United States and the European Union - and it seems there are no solutions to the problem, at least in the short term.[258]

In this case, the core of the matter is represented by the fact that the European institutions decided to ban chicken imports from the United States referring to the precautionary principle due to the alleged toxicity of substances used in the rinses. Yet, such a conclusion does not appear to be very solid under a scientific perspective, given the previously mentioned EFSA opinions and the lack of technical competence within the Council.

In so doing, the European Union provides for the range of American associations who currently claim for a market liberalisation with a legitimate reason to doubt on the real grounds of such a barrier. Effectively, it may be considered, in this view, a purely political ban established to protect the European economy.[259]

On its side, anyway, the European Union has an equally sustainable point to demonstrate the legitimacy of its position on chicken washing procedures, and it should try to explain it better and more.[260]

As a matter of fact, the European approach to food safety is generally more focused on the entire production and supply chain than the American one.

---

[256] Considering the allegation of United States, the Council decision may have violated Articles 2.2, 5 and 8 of SPS agreement as well as Article 8 of TBT agreement.

[257] *Dispute DS389 European Communities - Certain Measures Affecting Poultry Meat and Poultry Meat Products from the United States*.

[258] An idea may be to find an agreement similar to the so-called High quality beef's one, as mentioned in footnote 232. See also D. PISANELLO, *Happy end for US-EC dispute on poultry SPS measures*, Lex Alimentaria, August 24th 2011.

[259] See also R. HUNTER, *Why TTIP is stuck in the muck*, in *"Politico"*, January 16th 2016.

[260] Chancellor Merkel rigidly declared on May 24th 2014 that *"There will be no import of chlorine-washed chicken from the United States. There is no question about that."* See http://www.reuters.com/article/us-usa-eu-trade-merkel-idUSBREA4N07X20140524

In this sense, it may appear as more conclusive the view[261] according to which the simple final rinse of carcasses may not guarantee the salubrity standards conversely ensured by the European chain approach.[262]

Practically, the focus should be moved from the alleged (but never demonstrated) toxicity of chlorine solutions to their unproficiency in terms of food safety: thus, the European Union could more properly reject the American chicken considering the rinses procedure as not sufficient to fulfil the safety standards along the entire chain.

Coming to another much debated global topic, namely pesticides, according to reports from some newspapers[263], it seems that the presence of TTIP[264] on the horizon has concurred in blocking the enactment of a European regulation aimed to strongly limit the number of authorized pesticides within the European Union.

The point is quite tricky, considering that such substances represent a potential threat not just for the human health, but also for the environment.

In particular, with regard to risks linked to consumption of foodstuffs treated with pesticides, the biggest concern is about the effects of the so-called endocrine disruptors[265], which are those compounds capable of

---

[261] See the European Parliament resolution of 19 June 2008 on imports of poultry carcasses. The content of points 6 and 7 is quoted:
"The European Parliament,
[...]
6. Draws attention to the considerable investments made in this area by European poultry professionals, in accordance with Community legislation, with a view to reducing pathogen contamination by implementing a total food chain approach;
7. Considers the total food chain approach, as used within the European Union, to be a more sustainable means of reducing pathogen levels in poultry meat than decontamination using anti-microbial substances at the end of the food production process."

[262] This is the so-called from farm to table or from farm to fork approach often mentioned by Commission within the already cited White paper on food safety.

[263] One above all, see A. NELSEN, *EU dropped pesticide laws due to US pressure over TTIP, documents reveal*, in *"The Guardian"*, Brussels, May 22nd 2015.

[264] However, it has to be remembered that the draft text of the agreement does not foresee a special chapter on pesticides, given that United States and European Union are already working on this topic among both the OECD and the UN.

[265] In scientific literature they are identified with the acronym ECDs, which stand for Endocrine Disruptors Compounds.

considerably damaging the endocrine system interacting with the hormonal receptors.

The European Union regulates the use of such substances principally under two regulatory texts: reg. 1107/2009[266], which is more generally addressed to phytosanitary products, and reg. 528/2012[267], which deals only with that part of pesticides consisting of biocides. Next to both of them, the REACH system[268] provides for the registration, evaluation, authorization and restriction of chemical substances, requiring firms of the sector to perform regular risk assessment procedure.

On the American side, the most important regulatory acts which set the pesticides' registration procedure are the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)[269] and the above mentioned Federal Food, Drug and Cosmetic Act (FDCA).

The aspect of major difference between the American regulatory system and the European one can be found amongst chemical substance

---

[266] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. See also the related Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances and the Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides.

[267] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products Text with EEA relevance.

[268] See Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

[269] Federal Insecticide, Fungicide, and Rodenticide Act. An act for preventing the manufacture, sale, or transportation of adulterated or misbranded Paris greens, lead arsenates, and other insecticides, and also fungicides, and for regulating traffic therein and for other purposes, April 26th 1910, then amended by Federal Environmental Pesticide Control Act. An act to amend the Federal Insecticide, Fungicide, and Rodenticide Act, and for other purposes, October 21st 1972.

concentrations allowed in food.[270] As a matter of fact, considering the residue maximum levels of pesticides in food products prescribed by the American provisions[271], it is immediately evident that these numbers are basically higher than those foreseen by the respective European regulations.[272]

As noted above, indeed, thanks also to TTIP negotiations, the Commission missed an important deadline in December 2013 with regard to the proposition of criteria for detecting, among suspected substances, the endocrine disruptors.[273] Few months later, Sweden, followed by the Council of the European Union and the European Parliament, asked the Court of Justice of the European Union for a decision on such non-compliance.[274]

The most skeptical about the Commission's work have charged such a failure to pressures received from American government representatives and chemical industry, remarking the delay as totally groundless[275]; official sources from the Commission, instead, although not denying the contacts intervened with some American stakeholders, have not hesitated to define as mandatory a further reflection due to scientific uncertainty in the international debate.[276]

---

[270] They are the so-called maximum residue limits or maximum residue levels (MRLs) or, according to the American word, tolerances.

[271] See 40 CFR, Part 180.

[272] See the above mentioned Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC.

[273] See Article 5.3 of reg. 528/2012: *"No later than 13 December 2013, the Commission shall adopt delegated acts in accordance with Article 83 specifying scientific criteria for the determination of endocrine-disrupting properties."*

[274] Sweden brought the case to Court in May 2014, while the Council and the European Parliament join it in the first months of 2015.

[275] See S. HOREL, *A toxic affair. How the chemical lobby blocked action on hormone disrupting chemicals*, Corporate Europe Observatory, May 2015.

[276] So Bjorn Hansen, chief of unit A.3 of DG Environment. For further information, see *DG Environment explains delegated acts on biocides*, The Parliament Magazine, October 14th 2014.

Moreover, United States and European Union are nowadays particularly distant also with regard to levels of aflatoxins[277] allowed by the respective regulations within feeds and some kind of foods, in particular milk.

Responsible for an overwhelming poultry disease in 1960[278], such substances are known for the high toxicity level of two special varieties, namely B1, present in corn and other grains, and M1, which can be found in milk produced by animal fed with contaminated fodder.[279]

The European Union regulated the sector prescribing special limits for B1 aflatoxins in feeds[280] and more general maximum levels of aflatoxins in food.[281]

In the United States, the general responsibility regarding contaminants is on the FDA, which indeed set the maximum consented levels[282]; nevertheless, there is also a program[283] run by USDA which concurs in performing controls, reporting the results to FDA.

---

[277] Aflatoxins are a typology of highly toxic and carcinogenic mycotoxins produced by mushrooms and molds, particularly by *Aspergillus Flavus*, which gives the name to such substances. They colonize some kind of foods, as grains, nuts and maize, in particular where temperature is not really cold and the humidity level is high. There are six varieties of aflatoxins: B1, B2, G1, G2 plus the metabolic derivates M1 and M2. See also L. UNNEVEHR, D. GRACE, *Aflatoxins: Finding solutions for improved food safety*, International Food Policy Research Institute, September 30th 2013 e R. LAWLEY, *Aflatoxins*, in *"Food Safety Watch"*, February 1st 2013.

[278] In 1960, in a feedlot in England more than a hundred thousand turkeys died within a short time due to what was subsequently identified as a mycotoxins poisoning. Such substances were present in the groundnut meal within poultry feed. For a further reading of the case, see G. W. HUDLER, *Magical Mushrooms, Mischievous Molds*, Princeton University Press, 2000, pp. 86-89 and F. D. ASPLIN, R. B. A. CARNAGHAN, *The toxicity of certain groundnut meals for poultry with special reference to their effect on ducklings and chickens*, in *"Veterinary Record vol.73"*, 1961, pp. 1215-1219.

[279] Aflatoxins M1 is in fact a mutation of B1 variant, which is often present within feed used in feedlots.

[280] Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed.

[281] Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs.

[282] The last revision of consented limits dates back to 2005.

[283] It is the Grain Inspection, Packers and Stockyards Administration (GIPSA), settled in 1994 and included among the Marketing and Regulatory Programs. See also E. DOHLMAN, *Mycotoxin Hazards and Regulations. Impacts on food and animal feed crop trade*, in *"International Trade and Food Safety: Economic Theory and*

Lastly, *Codex Alimentarius*[284], which contains a series of guideline standards for members of the United Nations, has formulated some provisions regarding the maximum allowed levels, settling at values very close to the American ones - and much higher than the European ones.[285]

As can be easily perceived from the comparison between the following table, which reports the maximum levels of aflatoxins in American food and feed, and the one in the page after that, which summarizes the parameters set in the European Union, the first ones are in fact really higher and, so, more permissive.

Case Studies", Economic Research Service of USDA, November 2003, pp. 100-102.

[284] *Codex Alimentarius* was established in 1963 by Food and Agriculture Organization (FAO) and the World Health Organization (WHO).

[285] See in detail the following documents of Codex: *Code of Practice for the Reduction of Aflatoxin B1 in Raw Materials and Supplemental Feedingstuffs for Milk-Producing Animals, Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Peanuts, Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Tree Nuts, Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Dried Figs*.

Commodity	Level (ppb)
Corn and peanut products intended for finishing (i.e., feedlot) beef cattle	300
Cottonseed meal intended for beef, cattle, swine, or poultry (regardless of age or breeding status)	300
Corn and peanut products intended for finishing swine of 100 pounds or greater	200
Corn and peanut products intended for breeding beef cattle, breeding swine, or mature poultry	100
Corn, peanut products, and other animal feeds and feed ingredients but excluding cottonseed meal, intended for immature animals	20
Corn, peanut products, cottonseed meal, and other animal feed ingredients intended for dairy animals, for animal species or uses not specified above, or when the intended use is not known	20
Brazil nuts	20
Foods	20
Milk	0.5 (aflatoxin M1)
Peanuts and Peanut products	20
Pistachio nuts	20

Foodstuffs	Maximum levels (µg/kg)		
Aflatoxins	B_1	Sum of B_1, B_2, G_1 and G_2	M_1
Groundnuts to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs	8,0	15,0	—
Nuts to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs	5,0	10,0	—
Groundnuts and nuts and processed products thereof, intended for direct human consumption or use as an ingredient in foodstuffs	2,0	4,0	—
Dried fruit to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs	5,0	10,0	—
Dried fruit and processed products thereof, intended for direct human consumption or use as an ingredient in foodstuffs	2,0	4,0	—
All cereals and all products derived from cereals, including processed cereal products	2,0	4,0	—
Maize to be subjected to sorting or other physical treatment before human consumption or use as an ingredient in foodstuffs	5,0	10,0	—
Raw milk, heat-treated milk and milk for the manufacture of milk-based products	—	—	0,050
Following species of spices: *Capsicum* spp. (dried fruits thereof, whole or ground, including chillies, chilli powder, cayenne and paprika) *Piper* spp. (fruits thereof, including white and black pepper) *Myristica fragrans* (nutmeg) *Zingiber officinale* (ginger) *Curcuma longa* (turmeric)	5,0	10,0	—
Processed cereal-based foods and baby foods for infants and young children	0,10	—	—
Infant formulae and follow-on formulae, including infant milk and follow-on milk	—	—	0,025
Dietary foods for special medical purposes intended specifically for infants	0,10	—	0,025
Feed materials with the exception of:	0,05		
— groundnut, copra, palm-kernel, cotton seed, babassu, maize and products derived from the processing thereof	0,02		
Complete feedingstuffs for cattle, sheep and goats with the exception of:	0,05		
— dairy cattle	0,005		
— calves and lambs	0,01		
Complete feedingstuffs for pigs and poultry (except young animals)	0,02		
Other complete feedingstuffs	0,01		
Complementary feedingstuffs for cattle, sheep and goats (except complementary feedingstuffs for dairy animals, calves and lambs)	0,05		
Complementary feedingstuffs for pigs and poultry (except young animals)	0,03		
Other complementary feedingstuffs	0,005		

Within this last sector, a significant convergence of regulations, even in the real application moment of TTIP, appears as quite unrealistic, given the particular European sensitiveness to the problem.

As a conclusion to the various topics here faced, it has to be considered that in the draft of the treaty it is foreseen a horizontal chapter concerning the sanitary and phytosanitary measures.[286]

In the proposal released by European negotiators, the text contains some interesting news that however does not appear to differ so much from the SPS agreement's approach. Among the remarkable provisions, it is useful to underline those focused on the emergency measures[287], which requires a prompt communication to the other party and eventual technical consultations, as well as those establishing a Joint Management Committee (JMC)[288], composed of institutional and trade representatives of both the parties, which is responsible for coordination and direction in matter of sanitary and phytosanitary measures.

Thus, it seems very likely that most of these issues are not going to be treated directly within the TTIP, then again whereas no one wants to slow further the negotiating process; rather, they will be discussed afterwards, within the regulatory and institutional perimeter TTIP is going to create.

---

[286] This section has already been renamed by the insiders as SPS plus agreement. See A. ALEMANNO, *The Regulatory Cooperation Chapter of the Transatlantic Trade and Investment Partnership: Institutional Structures and Democratic Consequences*, Journal of International Economic Law, August 28th 2015, p. 5.

[287] *European Union Textual proposal on Sanitary and Phytosanitary measures (SPS)*, Article 16. It is quoted the full text:
"The importing Party may, on serious grounds, provisionally take emergency measures necessary for the protection of human, animal or plant health.
Emergency measures shall be notified to the other Party within 24 hours after the decision to implement them and, on request, technical consultations regarding the situation shall be held in accordance with Article 15 [Technical consultation]. The Parties shall consider the information provided through such consultations.
The importing Party shall:
a) Consider information provided, by the exporting Party when making decisions with respect to consignments that, at the time of adoption of emergency measures, are being transported between the Parties;
b) Consider the most suitable and proportionate solution for consignments in transport between the Parties, in order to avoid unnecessary disruptions to trade;
c) Revise or repeal, without undue delay, the emergency measures or replace them by permanent measures with a view to avoid unnecessary trade disruption."

[288] *Ibid.*, Article 18.

CHAPTER THREE

GENETICALLY MODIFIED ORGANISMS

It has already been mentioned how the delicate topic of genetically modified organisms may be considered as the bone of contention between two opposite conceptions which represent the acceptance or the refusal of the precautionary principle.[289]

As a matter of fact, while in the United States the impact of technology and, more particularly, of genetic engineering on the food sector has assumed over time so much importance to strongly influence cultivation and citizens' consumptions[290], the sensitiveness of European consumers and the environmental, social and economic concerns of political institutions have concurred hitherto in making the Old World not much permeable, from certain points of view[291], to genetically modified organisms.

It is, in fact, an issue that cannot be faced leaving aside neither the aspects related to side effects on environment and human health, nor the economic impact and the sociocultural components involved in such a discussion.

On this point, the matter of genetically modified organisms must be nowadays preceded by an indispensable premise which helps to clear away misunderstandings and to define the edge for a serious and profitable discussion.

---

[289] See pp. 8 and 46.

[290] As highlighted by data recollected by *"Statista"*, from 1997 to 2014 genetically modified crops in the United States have exponentially increased in terms of grown acres: HT soybean has passed from 17% to 94%, Bt cotton from 15% to 84%, HT cotton from 11% to 91%, Bt maize from 8% to 80% and HT maize from 4% to 89%. For full data see the page www.statista.com/statistics/217108/level-of-genetically-modified-crops-in-the-us.

[291] In the chapter it will be underlined as, actually, within the Union territories the real ban consists in GMOs cultivation and not in their presence in food (in any case very restrained) or feed (conversely very diffused).

In fact, given the special susceptibility to such topics not only of the academic and scientific sector, but also of the masses, very often uninformed or misinformed, it is not so rare for the observers to come across "news that were not"[292], rambling analyzes unsupported by scientific evidence or other kinds of hoaxes.[293]

The goal of this work, it goes without saying, is really far from furnishing the reader with a deep examination of the scientific aspects related to genetic modification techniques, what is anyway essential to express yourself with a quite certainty on the risks linked to such practices. Nonetheless, there are some fundamental aspects to take into consideration within such a wide multidisciplinary argument: thus, upon occasion, precise incursions into extra juridical areas have not been avoided - and they won't be avoided in the following pages.[294]

Anyhow, as said, the perspective used in this work focuses primarily on the regulation of genetically modified organisms as it has developed in the European Union and in the United States and on its practical consequences in terms of international trade relationships between these two superpowers.

In this view, it has to be considered what the real points under discussion are when debating about genetically modified organisms issues: in fact, if it is historically true that, on one side, the most attractive theme for public opinion regards the effects on human health[295], it is as much undoubted that a large part of debate is focused on environmental topics as

---

[292] The authorship of the expression has to be attributed to L. SOFRI, *Notizie che non lo erano. Perché certe storie sono troppo belle per essere vere*, Rizzoli, 2015.

[293] It has to be thought, for instance, of alerts like "GMOs are highly carcinogenic" as well as sensationalisms as "In few years GMOs could get rid of world hunger".

[294] See above all chapter 3.

[295] See R. PALMER, *GMO Health Risks: What The Scientific Evidence Says*, in *"International Business Times"*, March 30th 2013 and G. E. SÉRALINI, *Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize*, Food and Chemical Toxicology, November 2012. The latter pointed the finger at a genetically modified maize (maize NK603 owned by Monsanto) accused of having carcinogenic effects on rats, but was subsequently completely discredited by almost unanimity of scientific community and so withdrawn by the editor. Nevertheless, in June 2014 the research was republished in the journal *Environmental Sciences Europe*.

biodiversity or, moreover, on the positions of strength - and related weakness - which may occur between farmers and firms which own genetically modified seeds.[296]

In the following pages the differences between the European and the American genetically modified organisms regulatory frameworks will be pointed out; the international outcomes of such an opposition will be examined; finally, the most significant elements of such an analysis will be recollect in the light of the big picture represented by TTIP.

All the above without prejudices and *a priori* stances in favor or against such genetic engineering techniques applied to the food sector: it would be the worst way to deal with an issue that stimulates more than others the debate in public opinion.

1. TWO OPPOSITE REGULATIONS IN THE THROES OF AN INEVITABLE CONFLICT

The European regulation on genetically modified organisms has a relatively recent history, in the sense that it has come to constitute an independent and autonomous sector only from 2000s; previously, in fact, the matter was covered by reg. 258/1997[297], which dealt more generally with the so-called novel foods[298].

---

[296] For a critical opinion of the impact of genetically modified crops on the incomes of Italian farmers, see L. COLOMBO, *Grano o grane. La sfida OGM in Italia*, Manni Editori, 2006.

[297] Regulation (EC) n. 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients. Actually, previously there had already been a different act, the Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms, which will be under discussion in the following pages. Reg. 258/97 has been recently replaced by Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001.

[298] According to the provisions of Article 1 of reg. 258/1997 they are: "*[...] foods and food ingredients which have not hitherto been used for human consumption to a significant degree within the Community and which fall under the following*

The action of the European law-maker has been divided between regulations aimed at ruling on the use of genetic engineering techniques in farming and others committed to regulating genetically modified food and feed.

In the first of these two sectors the fundamental act is represented by Directive 2001/18[299], which, in addition to providing for a definition of what has to be considered as a genetically modified organisms[300], outlines an authorizing procedure for the market release of such organisms surrounded by special cautions.[301]

It has to be taken into account so far that this directive already foresaw, besides diffused recalls to precautionary principle[302], an explicit safeguard clause which allowed the Member States, in case of particular conditions such as the emersion of further scientific information, to limit or interdict

---

categories:
(c) foods and food ingredients with a new or intentionally modified primary molecular structure;
(d) foods and food ingredients consisting of or isolated from microorganisms, fungi or algae;
(e) foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use;
(f) foods and food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances."

[299] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC.

[300] See Article 2 of Directive 2001/18, which states that a genetically modified organisms is: *"an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination"*. Yet, it appears as particularly strange not only the exception foreseen in the following period, where in vitro fertilization, polyploidy induction and natural processes are not considered to result in genetic modification, but also and above all the exclusion provided by Article 3, according to which mutagenesis and plants cell fusion which can occur also through traditional reproductive techniques do not fall within the scope of the Directive. D. BRESSANINI, B. MAUTINO, *Contro natura. Dagli OGM al "bio", falsi allarmi e verità nascoste del cibo che portiamo in tavola*, Rizzoli, May 2015, pp. 118-124.

[301] See Articles 13, 19, 21 of Directive 2001/18 with regard to notification, authorization and labeling procedures. See also M. FERRARI, U.IZZO, *supra*, pp. 172-178.

[302] *Ibid.*, Articles 1 and 4.

the presence in the national territory of certain genetically modified organisms.[303]

Instead, with regard to genetically modified food and feed, reg. 1829/2003[304] foresees a system based on renewable ten-year temporary authorizations. They are released after a complex proceeding which involves the Commission, the EFSA and the competent authorities of each Member State, in full respect of the respective roles within the risk analysis procedures.

Avoiding spending too much time dwelling on the various phases of such a procedure[305], suffice it to consider here that the application for the authorization has to be addressed, together with copy of the studies performed on the particular food or feed, to the competent state authority, which shall inform the EFSA.[306] The latter is so supposed to release, within six months after having received the application[307], an opinion addressed to the Commission[308], which is competent for the final decision regarding the approval of the authorization.[309]

---

[303] *Ibid.*, Article 23: *"Where a Member State, as a result of new or additional information made available since the date of the consent and affecting the environmental risk assessment or reassessment of existing information on the basis of new or additional scientific knowledge, has detailed grounds for considering that a GMO as or in a product which has been properly notified and has received written consent under this Directive constitutes a risk to human health or the environment, that Member State may provisionally restrict or prohibit the use and/or sale of that GMO as or in a product on its territory. [...]"*

[304] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed.

[305] Despite the presence of two different procedures for food and feed, there are not big differences between them.

[306] Reg. 1829/2003, Article 5. It has to be noted that, in addition to copy of the studies carried out, the applicant must provide a reasoned analysis which testify that the characteristics of the food are not different from its traditional version.

[307] *Ibid.*, Article 6. In case of positive opinion, EFSA forwards a proposal for the label of the product.

[308] More precisely, the decision requires the involvement of the Standing Committee on the Food Chain and Animal Health established under the Article 58 of reg. 178/2002, which flank the Commission.

[309] *Ibid.*, Article 7. In case of approval, the Commission provides also for the insertion of the food in the proper register.

For the purpose of this work, what is important to underline is the fact that within the European Union it is not allowed to cultivate, sell or utilize genetically modified organisms without a prior institutional permission: this is an evident sign of the European legal system's disfavor towards the application of genetic engineering techniques in the food sector.

Such an approach appears to be even more radical considering that, once obtained the authorization for the market release of a genetically modified organism, reg. 1830/2003[310] provides for a special labeling and traceability system, requiring for indicating the presence of such an organism within food and feed.[311]

Yet, it has to be noted a clamorous discrepancy: despite the constraint to indicate in feed labels the presence of genetically modified components, such an obligation does not exist with reference to food products derived from animals which have been fed with such fodder.[312] This is a failure that starkly clashes with the generally suspicious approach of the European Union with regard to genetic manipulation of seeds[313], especially considering that the European demand for feed is primarily satisfied with imports from country dominated by transgenic crops.[314]

---

[310] Regulation (EC) n. 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.

[311] See Article 4.6 of reg. 1830/2003: *"For products consisting of or containing GMOs, operators shall ensure that:*
(a) for pre-packaged products consisting of, or containing GMOs, the words 'This product contains genetically modified organisms' or 'This product contains genetically modified [name of organism(s)]' appear on a label;
(b) for non-pre-packaged products offered to the final consumer the words 'This product contains genetically modified organisms' or 'This product contains genetically modified [name of organism(s)]' shall appear on, or in connection with, the display of the product. [...]"

[312] The only products surely derived from animals fed with GM-free fodder are those which are certified as organic. See D. BRESSANINI, *Il Made in Italy contaminato dagli OGM*, in *"Scienza in cucina"*, July 15th 2013.

[313] Currently in fact the only genetically modified organisms of which the cultivation is permitted is MON810 maize owned by Monsanto, which grows in five Member States and represents around 1,5% of the overall European corn crops area.

[314] On this point, see data released by Communication COM(2015) 176 from the Commission to the European Parliament, the Council, the European Economic and

Anyhow, this procedural mechanism has had to deal, during years, with a well-established reality within the European landscape, namely the polarization of the dialogue on genetically modified organisms, which has concurred in creating blocks of countries in favor, like Spain, Czech Republic and United Kingdom, and against, like Austria, Italy and France.[315]

Such a division did not hesitate to have repercussion on the institutional level, engendering a sort of anomaly in the European authorizing process: in fact, each Member States is called to vote a draft of the Commission's decision within the standing committee[316] and, where a qualified majority in favor or against the authorization cannot be reached, the Commission is required to definitively decide the matter.

The point is that, since reg. 1829/2003 entered in force, the standing committee has never been able to express a qualified majority in neither sense, with the result that the Commission has been following a very conservative praxis over time, postponing as much as possible its decision and ending with slavishly compelling with the scientific opinion provided by EFSA.

This issue derives from the fact that often States' objections are not based upon "legitimate factors" as those which the Commission may take into account under Article 7[317] of reg. 1829/2003 and the related cases on trade

---

Social Committee and the Committee of the Regions reviewing the decision-making process on genetically modified organisms of April 22nd 2015.

315 On this theme, see D. BRESSANINI, *Mais OGM: un bigino per i neoministri*, in *"Scienza in cucina"*, April 25th 2014.

316 See note n. 308. Where at this level a decision is not adopted or a negative qualified majority is expressed, the Commission can invest the Appeal Committee of the matter.

317 An excerpt of the text is reported: "*Within three months after receiving the opinion of the Authority, the Commission shall submit to the Committee referred in Article 35 a draft of the decision to be taken in respect of the application, taking into account the opinion of the Authority, any relevant provisions of Community law and other legitimate factors relevant to the matter under consideration. Where the draft decision is not in accordance with the opinion of the Authority, the Commission shall provide an explanation for the differences.*"

restrictions[318], but on economic and political considerations mostly linked to commercial stakes of the individual Member Countries of the Union.

Analogously, the same problem recurs when the States adopt emergency measures as those foreseen by Article 34[319] of reg. 1829/2003 in order to ban the cultivation or the market release into the national territory of genetically modified organisms: they are indeed political, economic and social reasons, but the governments of Member States cannot disclose them.

Such critical issues have contributed to initiate a serious discussion among the Member States in order to reform the regulatory framework of genetically modified organisms: on one side, in fact, the Union cannot give up on maintaining a centralized authorizing procedure; on the opposite side, the situation has become unacceptable for the States against, which have not a way to leverage stakes other than the environmental or the public interest ones foreseen by the European disposition, and for the States in favor too, which assist to a slowdown in the biotechnological progress.[320]

This debate has recently resulted in the adoption of Directive 2015/412[321], which institutionalizes the compromise reached between the two blocks and applies the system of "two-speed" Europe[322] to the sector

---

[318] See above all the interpretation of Article 30 TEC (now Article 34 TFEU) given by the above mentioned *Cassis de Dijon* case.

[319] Here is the full text: "*Where it is evident that products authorised by or in accordance with this Regulation are likely to constitute a serious risk to human health, animal health or the environment, or where, in the light of an opinion of the Authority issued under Article 10 or Article 22, the need to suspend or modify urgently an authorisation arises, measures shall be taken under the procedures provided for in Articles 53 and 54 of Regulation (EC) No 178/2002.*" See also M. FERRARI, U. IZZO, *supra*, p. 176.

[320] See also J. LAU, *Same Science, Different Policies: Regulating Genetically Modified Foods in the U.S. and Europe*, in *"Science in the news"*, August 9th 2015.

[321] 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.

[322] "Two-speed" Europe consists in the idea that community integration has to go on in a different measure and way according to the peculiarities of the individual

of genetically modified crops: in fact, maintaining the authorizing mechanism set by Directive 2000/18, the Member States are allowed to prohibit cultivation on national area also on the basis of further elements than those evaluated by EFSA.[323]

Similarly, for genetically modified food and feed, it is currently under discussion a proposal for a regulation[324] which retraces the same variable geometry mechanism applied for genetically modified crops.

It has been so discovered that the European Union's position on genetically modified organisms is actually far from being homogenous: even though, in fact, the regulatory framework is undoubtedly influenced by the precautionary principle and by the view of genetic engineering as a risk factor for consumers, the number of countries which do not want to renounce to use such technologies in the food sector is increasing.

Actually, the current situation, where almost all the European cultivations are conventional[325] and, at the same time, a large amount of products containing or deriving from genetically modified organisms is peacefully

---

Member States. Far from being a mere theoretical riddle, such a conception is an established reality in several sectors of the European Union competence. To go further, see the article appeared on *"The Economist"* on February 1st 2007, titled *Coalition for the willing*.

[323] It is in fact added the Article 26 *ter* within the Directive 2001/18, whose subparagraph 3 states: *"[...] a Member State may adopt measures restricting or prohibiting the cultivation in all or part of its territory of a GMO, or of a group of GMOs defined by crop or trait, once authorised in accordance with Part C of this Directive or with Regulation (EC) No 1829/2003, provided that such measures are in conformity with Union law, reasoned, proportional and non-discriminatory and, in addition, are based on compelling grounds such as those related to:*
(a) environmental policy objectives;
(b) town and country planning;
(c) land use;
(d) socioeconomic impacts;
(e) avoidance of GMO presence in other products without prejudice to Article 26a;
(f) agricultural policy objectives;
(g) public policy."

[324] See COM(2015) 177 final - Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 1829/2003 as regards the possibility for the Member States to restrict or prohibit the use of genetically modified food and feed on their territory of April 22nd 2015.

[325] See note n. 313.

imported from third countries, cannot certainly be considered as a satisfying one for the economy of the European Union.

Instead, with regard to the American regulation, the recent positions of the Congress with regard to labels on genetically modified food[326] may seem going exactly in the opposite direction of the "multi-speed" strategy adopted by the European Union.

Anyway, it is better to proceed orderly, starting from the institutional and regulatory architecture on genetically modified organisms established over years in the United States.

As previously pointed out[327], the division of powers among the several American agencies dealing with the food sector is highly fragmented.

The matter of genetically modified organisms does not constitute an exception[328], considering that three federal agencies are involved: the EPA, which deals with the risks for human health and environment deriving from pesticides and microorganism created through genetic engineering techniques[329]; the USDA, which, through the Animal Plant Health Inspection Service (APHIS) is committed to defending the American territory from the diffusion of noxious weed[330]; the FDA, which guarantees the safety of substances added to food. For the purposes of this work, the latter, namely the human consumption of genetically modified food, will be the most stressed topic.[331]

---

326 See note n. 101.

327 See p. 54.

328 For the big picture on the American regulation of the genetically modified food, see M. FERRARI, U. IZZO, *supra*, pp. 178-184.

329 See also L. ACOSTA, *Restrictions on Genetically Modified Organisms: United States*, Library of the Congress, March 2014.

330 Here is the text of Title 7, sub 7712(a) of U.S. Code: *"The Secretary may prohibit or restrict the importation, entry, exportation, or movement in interstate commerce of any plant, plant product, biological control organism, noxious weed, article, or means of conveyance, if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction into the United States or the dissemination of a plant pest or noxious weed within the United States."*

331 For a quite critical point of view regarding the fragmentation of competences and the poorness of the federal agencies' controls on genetically modified organisms, see R. M. BRATSPIES, *Is anyone regulating? The curious state of GMO governance in the United States*, Vermont Law Review vol. 37, 2013 pp. 923-956.

The first element to start from in order to explain the evolution of the American regulation is the fact that it has its roots, more than in a clear political vision[332], in the response to a lawsuit filed against the federal government due to the first field test of genetically modified organisms.

In fact, in the early 1980s, following the authorization for the usage of a bacterium called Ice-minus[333] released by the National Institute of Health (NIH)[334], an American foundation[335] brought the case to the federal court alleging that NIH had granted the permission without performing an adequate environmental impact assessment.[336]

Subsequently the decision, which brought to the light the failures of the NIH, the Reagan Administration enacted in 1986 a document titled Coordinated Framework for the Regulation of Biotechnology (CFRB)[337], which provided - and provides nowadays - with the guidelines on regulation of genetically modified organisms.

Such principles, definitely incisive for the American approach to biotechnology, can be essentially summarized in four assumptions: first, the genetic engineering techniques do not necessarily imply ulterior specific risk than the traditional techniques; second, regulations on the

---

[332] To go in depth on the American regulatory framework, see D. LYNCH, D. VOGEL, *The Regulation of GMOs in Europe and the United States: A Case-Study of Contemporary European Regulatory Politics*, Council of Foreign Relations Press, April 5th 2001.

[333] This bacterium, a variant of the common bacterium *Pseudomonas syringae*, had been deprived of a gene present in the natural version which facilitates ice crystals formation on cultivate plants. The so obtained Ice-minus would have been sold under the name Frostban, given its propensity to impede ice formation on crops.

[334] At that time, the NIH was the only federal agency committed to regulating on biotechnology.

[335] It was the Foundation on Economic Trends (FET), chaired by its owner, the activist Jeremy Rifkin.

[336] Foundation on Economic Trends v. Heckler (Heckler I), 587 F. Supp. 753, 755 (D.D.C. 1984), affd, 756 F.2d 143 (D.C. Cir. 1985). To go in depth see E. PIZZULLI, *Foundation on Economic Trends v. Heckler: Genetic Engineering and NEPA's EIS Requirement*, Pace Environmental Law Review vol. 2, 1984, pp. 138-165 and S. PENDORF, *Regulating the environmental release of genetically engineered-organisms: Foundation on Economic Trends v. Heckler*, Florida State University Law Review, 1985, pp. 891-921.

[337] Coordinated Framework for Regulation of Biotechnology, 51 Federal Register.

matter may be focused on the product itself and not on the process[338]; third, the existing provisions are sufficient for regulating products of biotechnology; fourth, eventual regulatory gaps may be fulfilled through cooperation between agencies.[339]

Given these basic directives, the FDA has the task to prohibit, according to the provisions of the above mentioned FDCA, adulterated food, scilicet that food to which substances that can make it dangerous for human health have been added.[340]

Yet, among these additives the FDCA introduces a clear distinction: on one side, in fact, there are the so-called food additives[341], which are required to pass a pre-market approval[342] in order to testify the absence of risks linked to human consumption; on the other side, the so-called GRAS[343] are instead exempted from such a procedure where they do not differ in a substantial manner from conventional food.[344]

---

338 It has to be noted the evident contradiction with the chain approach adopted in the European food law, mentioned in note n. 262.

339 See R. M. BRATSPIES, *Some thoughts on the American approach to regulating genetically modified organisms*, Kansas Journal of Law & Pubic Policy vol. 16, 2007 and M. FERRARI, U. IZZO, *supra*, p. 179.

340 Title 21, section 342(a) of U.S. Code.

341 Here is an excerpt of the content of Title 21, section 321(s) of U.S. Code: *"The term "food additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use [...]"*.

342 Title 21, section 409 of *U.S. Code*.

343 Generally Recognized As Safe.

344 It has to be noted as, ultimately, each producer can *de facto* decide whether apply for the authorization of the additive or starting to sell it as GRAS. See also M. FERRARI, U. IZZO, *supra*, p. 182.

In line with the provisions of CFRB, FDA enacted in 1992 a Statement of Policy[345] concerning food derived from new plant varieties as those genetically manipulated, basically confirming the substantial equivalence between traditional products and genetically modified organisms and considering the latters as GRAS.

The consequences of such provisions consist in the fact that, nowadays, producers who want to sell genetically modified organisms can do it without any sort of mandatory prior authorization or consultancy of FDA.[346] The primary role in carrying out the risk assessment phase is thus held by private operators.

Considering more directly the issues on genetically modified organisms labeling, at this point it goes without saying that neither an autonomous and separate traceability system, nor a duty to indicate on the label the presence of genetically modified components is required by law.

Moreover, such a practice might be considered even unlawful in the opposite sense, i.e. adopting expressions such as GM-free, due to the deceptive effect on consumers: indeed, there would not be elements[347] that justify the indication of this characteristic of the product, taking into account the substantial equivalence of this food with the traditional one.

Nevertheless, American public opinion is not indifferent to these themes[348] and this fact has pushed some American States to enact special

---

345 Statement of Policy - Foods Derived from New Plant Varieties, Federal Register vol. 57, May 29th 1992.

346 Producers can decide to voluntary ask the FDA for a consultancy, without any kind of constraint with regard to data to submit or tests to carry out. Such a mechanism has been criticized also by FDA itself, which in 2001 proposed to make compulsory this process, providing at the same time the agency with the power to define a food as GRAS. These efforts were undermined by the withdrawal of the proposal by the incoming Bush Administration. For further information, see *Proposed Rule: Premarket Notice Concerning Bioengineered Foods*, Federal Register vol. 66, January 18th 2001.

347 It is anyhow mandatory to indicate the presence of certain substances in relation to possible food allergies.

348 A large amount of pools and consultations has been carried out in last years with regard to labels for genetically modified organisms, observing that on average more than nine out of then Americans are in favor of the introduction of such information on labels. Above all, see *Consumer Support for Standardization and Labeling of Genetically Engineered Food,* Consumer Reports National

regulations which constrain producer to indicate on the label the presence of genetically modified components in food.[349]

Such efforts are nowadays endangered by a bipartisan proposal for a federal regulation[350] already approved by the House of Representatives and currently deposited in Senate, the so-called Safe and Accurate Food Labeling Act. This proposal is strongly opposed by a large portion of public opinion and by several no-profit associations[351], due to the provision which would establish a unique and voluntary labeling system that may impede the States to introduce more stringent compulsory requirements.

Recapping, it is evident that United States and European Union has concurred over time to sharpen the differences between respective regulations on genetically modified organisms.[352]

First of all, unlike the United States, where a real prior authorizing procedure for market release does not exist, in the Old World the historical skepticism of political institutions has contributed to create a rigorous prior evaluation mechanism; furthermore, it is useful to note that the difference between the approaches is definitively attributable to the difference in the regulation subject - a product, on one side, and a process, on the other -[353]; finally, as a logical consequence of the exposed contents, information for the consumer through food labels are really developed only on the European side.[354]

Research Center, 2014 e *National survey of healthcare consumers: genetically engineered food*, Thomson Reuters, October 2010.

349 See note n. 100.

350 See note n. 101.

351 Above all, see the organization Just Label It!, born to promote public opinion awareness on labeling genetically modified food.

352 For a comparison between the two regulations, see also D. WIRTH, *The Transatlantic GMO Dispute Against the European Communities. Some Preliminary Thoughts*, in *"EU and WTO Law: How Tight is the Legal Straitjacket for Environmental Product Regulation?"*, Brussels University Press, 2006.

353 See also M. FERRARI, U. IZZO, *supra*, p. 179.

354 Despite some exceptions. See p. 86, notes n. 312, 313 and 314, as well as note n. 346.

On the background, the leitmotif represented by the precautionary principle, whose application resulted in a bitter international dispute between European Union and United States.[355]

In the early 1990s, in fact, the release of genetically modified organisms into the European environment was still covered by Directive 90/220[356], whose main features were not so different from the American regulation, except for a particular provision[357] which allowed the individual Member States to provisionally ban on their territories an organism already authorized by the Commission.

Despite some attempts on regulatory cooperation among the above mentioned TEP from both the parties' institutions[358], some European States, among which Austria, France, Germany and Italy, between 1997 and 1998 started to prohibit a series of genetically modified organisms on their national territories on the ground of the clause of Directive 90/220.

At the same time, the European Union was working on a legislative reform which would have resulted in the Directive 2001/18.

The situation went on so far that in 1999 five Member States[359] released a joint declaration which expressed their concerns about the adequacy of the reform in progress and confirmed their commitment to impeding, within their borders, the emission of genetically modified products, according to

---

[355] For a further reading on the dispute, see F. SINDICO, *The GMO Dispute before the WTO: Legal Implications for the Trade and Environment Debate*, Fondazione Eni Enrico Mattei, January 2005.

[356] See note n. 297.

[357] It is the Article 16 of Directive 90/220: "*Where a Member State has justifiable reasons to consider that a product which has been properly notified and has received written consent under this Directive constitutes a risk to human health or the environment, it may provisionally restrict or prohibit the use and/or sale of that product on its territory. It shall immediately inform the Commission and the other Member States of such action and give reasons for its decision.*
A decision shall be taken on the matter within three months in accordance with the procedure laid down in Article 21.

[358] In 1998 TEP established a Biotechnology Working Group with the task to develop a uniform procedure to regulate genetically modified organisms. See also M. J. PETERSON, *The EU-US Dispute over Regulation of Genetically Modified Organisms, Plants, Feeds, and Foods - Case Summary*, International Dimensions of Ethics Education in Science and Engineering, 2010, p. 6.

[359] They were Denmark, Greece, France, Italy and Luxembourg.

the precautionary principle; meanwhile, other seven European States[360] declared the intention to adopt a rigorous precautionary approach in reviewing each single authorization.[361]

This led to a real moratorium against the usage of genetically modified organisms, which, together with the more stringent requisites introduced by Directive 2001/18, was immediately considered by the United States as an unlawful trade restriction.

The American government reacted, as the Canadian and the Argentinian ones[362], calling on the WTO, which established a panel in August 2003.[363]

The complaint of United States was essentially focused on the alleged lack of scientific grounds in several decisions whereby the European Union had refused to authorize some genetically modified organisms over time[364], as well as in the position of some European States, reluctant to accept the presence of such organisms within their territories.[365]

Conversely, the European Community rejected the idea of a "blank" moratorium[366], recalling international documents other than those

---

[360] They were Austria, Belgium, Finland, Germany, Netherlands, Spain and Sweden.

[361] See D. WIRTH, *The World Trade Organization Dispute Concerning Genetically Modified Organisms: Precaution Meets International Trade Law*, Vermont Law Review vol. 37, 2013, p. 1180.

[362] Actually, Canada and Argentina established two ulterior and separated procedures, respectively indicated as WT/DS292 and WT/DS293.

[363] Dispute DS291 - European Communities - Measures Affecting the Approval and Marketing of Biotech Products.

[364] Since October 1998, in fact, no more authorizations for genetically modified products had been released.

[365] In particular, the position of United States did not appear to be incompatible with a general precautionary approach regarding the risk assessment phase. Rather, the American government considered as inconceivable its extension to the risk management stage too. On this point, see n. 4 of the Summary of COM(2000) 1: *"The precautionary principle should be considered within a structured approach to the analysis of risk which comprises three elements: risk assessment, risk management, risk communication. The precautionary principle is particularly relevant to the management of risk."*
See also L. KRÄMER, *The Roots of Divergence: a European Perspective*, in *"Green Giants? Environmental Policies of the United States and the European Union"*, MIT Press, 2004, pp. 68-69.

[366] The European Community indicated the example of Bt-11 maize, authorized in May 2004, to bear that actually the followed approach tended however to evaluate case by case the applications. See also M. J. PETERSON, *supra*, p. 9.

previously taken into account[367], among which the Convention on Biological Diversity[368] and the related Cartagena Protocol on Biosafety[369], in order to corroborate the lawfulness of its policies.[370]

The final report containing the findings of the panel, released in 2006, effectively recognized the existence of a *de facto* moratorium and remarked also its inconsistency with the SPS Agreement due to the "undue delay" so engendered in the procedure for the approval of genetically modified products.[371]

Nevertheless, the report considered the responsibility of the European Commission differently than the Member States' one: in fact, if on one side it was remarked as the action of the latter was justified by the lack of scientific evidence under Article 5.7, and thus it resulted in a violation of Articles 2.2 and 5.1, on the other side the position held by the Community was not blamed, since the adopted measures were not sanitary or phytosanitary and so they could not constitute a violation of the same provisions.[372]

On the ground of these findings, parties agreed to define a reasonable period of time for the Commission to conform the European regulation

---

[367] United States in fact had based their claim on some provisions of AoA, GATT (1994), SPS and TBT agreements.

[368] Convention on Biological Diversity (CBD), Rio de Janeiro, June 5th 1992.

[369] Cartagena Protocol on Biosafety to the Convention on Biological Diversity (CPB), Montreal, May 15th 2000. Here is the text of Article 1: *"In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements."* See also note n. 16.

[370] However, it has to be noted that the United States, although having signed the Convention, has never ratified it. As a consequence of that, they cannot be considered as part of the Protocol.

[371] The "undue delay" provision can be found in Article 8 of SPS Agreement, as well as the related Annex C. The panel considered the European regulation as well as Member States which had impeded the usage of genetically modified products on their territories as responsible for such a delay.

[372] WT/DS291/R European Communities - Measures Affecting the Approval and Marketing of Biotech Products - Reports of the Panel, September 29th 2006.

to the report contents. However, following the unsuccessful expiration of the deadline, in January 2008 the United States agreed to the proposed compensation mechanism[373] intended to partially repair the Commission delay.[374]

2. A HARD COMPROMISE IN THE SHORT TERM

In light of the foregoing, it may appear as at least fanciful to hypothesize the achievement of an agreement on food biotechnology between United States and European Union. Rather, it may be argued without exaggeration that a compromise, in this matter, is anything but expected.
According to what has been publicly declared through the official channels of the Commission[375], in fact, the prior authorizing system established by the European Union will not be changed under TTIP. This appears as quite obvious, whatever various opponents of the treaty say, albeit some exceptions[376], with enviable *sicumera*.[377]

---

[373] See Articles 21 and 22 of DSU.

[374] On this point, see M. A. POLLACK, G. C. SHAFFER, *When Cooperation Fails: The International Law and Politics of Genetically Modified Foods*, Oxford University Press, May 21st 2009, p. 226-227.

[375] Factsheet on Food safety and animal and plant health in TTIP, European Commission: *"Growing genetically modified organisms is subject to an authorisation process in line with EU law. TTIP will not change this law. EU countries must also agree to any growing of GM plants. This will not change through TTIP."* See also the article of F. RAMPINI, *TTIP, la posta in gioco*, in *"Estremo Occidente"*, April 20th 2015, available on the author's blog at the page www.rampini.blogautore.repubblica.it/2015/04/20/ttip-la-posta-in-gioco.

[376] See M. DI SISTO, *Contro il TTIP, con i piedi per terra. Sovranità, agricoltura, OGM, cibo: tutto quello che vorreste sapere sul negoziato USA e UE e vi stanno raccontando solo in parte*, Fairwatch, February 23rd 2014. The author, vice president of one of the associations which adhere to Stop-TTIP campaign, highlights as it is likely that the discussion on genetically modified organisms will be postponed and remitted to the Regulatory Cooperation Body mentioned at note n. 127.

[377] What the voices against the conclusion of the treaty seems to ignore is, among other things, that United States cannot afford to waste more time in negotiating, for the reasons listed in notes n. 98, 107 and 108, so it is unlikely that a highly divisive theme as the genetically modified organisms' one will be put on the negotiation table for a global review. For a contrary point of view, see the article

Nevertheless, this does not mean that negotiators could not talk of genetically modified organisms at all or that the proper application phase of the treaty, that is when common regulations based on the provisions of the regulatory chapter of TTIP will be outlined, could not involve this sector: however, even then the European and American legislative prerogatives may not be debased in the name of global harmonization.[378]

Effectively, a certain thaw between the two superpowers has already been noticed following the WTO decision of 2006, when representatives of the parties began to meet in order to find a solution to the issue: actually, neither of them would have gained something in trigger an expensive trade war, given that, on one side, the products involved in the dispute were considered as substantially overcome in the American market by then and, on the other, the impact of possible compensatory measures frightened the European institutions.[379]

Thus, currently the European Union seems to have soften its position regarding the authorization of genetically modified organisms, due also to the clamor engendered by such an international issue; anyway, this does not coincide with a parallel commercial acceptance of them among the European consumers.[380]

Such a situation is not only to be considered as unsatisfying for the American commercial stakes, but it also put the Commission, yet committed to reviewing the authorizing process, into the tough position

---

of Greenpeace, *TTIP, non erano esclusi gli OGM?,* in *"Il fatto quotidiano",* May 4th 2015.

[378] See note n. 129.

[379] See M. A. POLLACK, G. C. SHAFFER, *supra*, pp. 225-226. On these grounds may be justified also the authorization of Bt-11 maize in note n. 366.

[380] See the European Commission poll on Biotechnology resulted in a report published in October 2010, which underlines the diffused skepticism of European consumers regarding genetically modified food: *"The survey reveals an overall suspicion of GM foods amongst the European public. A high proportion, 70%, agrees that GM food is fundamentally unnatural. 61% of Europeans agree that GM food makes them feel uneasy. In addition, 61% of Europeans disagree that the development of GM food should be encouraged, 59% disagree that GM food is safe for their health and that of their family, and 58% disagree that GM food is safe for future generations."*

of risking to have to leave more autonomy - as after all occurred with Directive 2015/412 - to Member States in managing the issue.

These last reforms, in fact, have concurred in increasing the American TTIP negotiators' concerns[381] with regard to a sector where a compromise may be hardly found, especially considering the drop in exports towards European Union suffered following the moratorium.[382]

Therefore, two further considerations must be added.

The first one concerns the increasing number of American farmers and firms which, given the unpredictability and the sternness of the European authorization mechanism for genetically modified seeds, have started to cultivate *also* conventional crops, in order not to be excluded from the European market.[383] Nevertheless, this surely cannot be a long term solution and, indeed, it contributes to create an economic burden for such operators, forced to differentiate the production, duplicating part of the production processes.

The second refers to the effect caused by the exclusion of the European Union from a fast growing global market, namely the food biotechnology's one.[384] The strong skepticism that winds in Europe has in fact impeded over years the adequate development - *rectius*, the funding - of cutting edge studies on food biotechnology.[385]

Negotiators have so more than a good reason to try to improve an unsatisfying situation for both the parties; nonetheless, neither the

---

[381] The official representative for the United States Michael Froman so expressed himself on the Directive 2015/412: "*We are very disappointed by today's announcement of a regulatory proposal that appears hard to reconcile with the EU's international obligations. Moreover, dividing the EU into 28 separate markets for the circulation of certain products seems at odds with the EU's goal of deepening the internal market*".

[382] United States in 1996 exported soy in Europe for the value of 2,3 billion dollars. In 2004 this value decreased to 850 million dollars. See M. A. POLLACK, G. C. SCHAFFER, *supra*, p. 83.

[383] See M. A. POLLACK, G. C. SCHAFFER, *supra,* p. 277.

[384] On this point it is eloquent the position of former European Commissioner for Trade Peter Mandelson in a press release dated June 14th 2007: "*We must be under no illusion that Europe's interests are served by being outside a global market that is steadily working its way through the issues raised by GM food. They are not.*"

[385] See D. BASSANINI, B. MAUTINO, *supra*, pp. 299-303.

European Union, nor the United States seems to be willing to upset their regulatory frameworks on genetically modified organisms for the sake of an agreement with the respective partner.

On this point, it has to be noted a deep difference between the American strategy and the European one: while the first succeeded in involving the main firms of the sector, engaging them in a strong lobby action which has contributed to pave the way for the official negotiators[386], the European institutions cannot count on an unitary political framework, having rather to face the wide division between association in favor of the agreement and associations against it. The Union so appears to be weaker, because less united, at the negotiating table.

Anyhow, as previously noted, it is reasonable to expect that the final text of the treaty may not contain great revolutions on the matter; rather, an interesting suggestion on the results of such a dialogue may be found out in the recent agreement between Canada and European Union, namely the CETA.

In fact, in the consolidated text of this treaty it has been included a proper chapter on regulatory cooperation[387], which contains a special section concerning biotechnology.

Here there is an express recall to the WTO dispute and to the dialogue following the related decision, in order to remark the commitment of the parties to discuss topics such as the mechanism for the approval of biotechnology products, the adoption of new sectoral regulation or the measures implemented by the individual Member States of the Union.[388]

---

[386] In this sense may be read for instance the letter sent in February 2015 to the Commission from 13 large firms which complained about the delay of European institutions in the approval of genetically modified organisms, as well as the several email exchanges between political bodies of the Union and American industry associations. See also *Transatlantic Trade and Investment Partnership (TTIP) Could Open EU to 'New Biotech' GMO Seeds and Foods,* in *"Global Research News"*, July 2nd 2015.

[387] See point 29 (Dialogues and Bilateral Cooperation) of CETA, pp. 442-445.

[388] *Ibid.*, Article X.03 (Bilateral Cooperation on Biotechnology). Here is an excerpt of the provision: *"[...] The dialogue covers any relevant issues of mutual interest to Canada and the EU, including, among others:*
- biotechnology product approvals in the territory of Canada or the EU as well as,

A similar choice may be made even with reference to TTIP, *de facto* delegating the real discussion on the contents to the Regulatory Cooperation Body.

This may facilitate the job of the representatives under two perspectives: first of all, it would consent to go on in negotiating without running the risk to be slowed down by a tricky discussion on some hot topics as this one; secondly, working on a theme which is so interesting for public opinion, especially for the European one, would be really easier once the media attention for the TTIP discussion will be waned.

Therefore, there should not be a revolution in the field of genetically modified organisms just due to the content of TTIP; the gaze should be turned beyond, towards the regulatory cooperation process which will be established under the treaty.

---

where appropriate, forthcoming applications of commercial interest to either side;
- the commercial and economic outlook for future approvals of biotechnology products;
- any trade impact related to asynchronous approvals of biotechnology products or the accidental release of unauthorised products, and any appropriate measures in this respect;
- any biotech-related measures that may affect trade between Canada and the EU, including measures of EU Member States;
- any new legislation in the field of biotechnology; and best practices in the implementation of legislation on biotechnology."

CHAPTER FOUR

GEOGRAPHICAL INDICATIONS

The last of the aspects considered in this work is represented by geographical indications. Yet, it is necessary to spend some words about the meaning of the term geographical indication, since it tends to expand or shrink, even indicating very different legal institutes, depending on the regulation and therefore, often, on the place referred to.[389]

For the purposes of these pages, it will be used the concept of geographical indications with regard not only to those ones established by the European regulations in order to protect quality food products, but also to what is foreseen under American law and by some international provisions concerning intellectual property.

What can be considered as the common thread of these declinations is the distinctive function they grant, focused on the link between the territory of origin of a particular product and its quality.[390]

In the following pages, particular attention will be primarily paid to regulations issued on this matter by the European Union and the United States, highlighting the deep differences between them; subsequently, a special section will be dedicated to the international regulatory framework of geographical indications; then a special focus will be reserved for the case of wine products; finally, the respective starting positions will be reconsidered in the light of the negotiation of the Transatlantic partnership.

---

[389] On this point, see more specifically M. FERRARI, *La dimensione proprietaria delle indicazioni geografiche. Uno studio di diritto comparato,* Editoriale Scientifica, 2015, pp. 29-31.

[390] On the link between product and territory see note n. 4.

1. AN ADVANCED PROTECTION SYSTEM AND AN (ALMOST) ABSENT PROTECTION SYSTEM

Within the European Union it has been developed a proper *sui generis* protection system for geographical indications of agricultural and food products.

This particular legal framework reflects, under a certain point of view, the strong sensitivity of the States of the Old World for everything concerning food, tradition and quality *in primis*.

With reference to the concept of quality[391], indeed, over time the European institutions have focused their efforts in the food sector on a quality competitive production rather than on a quantity production[392]: the system of geographical indications seems to be so far the best tool for pursuing such policies.[393]

However, over the years institutions and Community courts as well have been using the term *quality* referring to different aspects.

If at first, in fact, the Commission preferred to protect the particular geographical origin only where such an origin would have conferred or would have contributed to confer special and valuable organoleptic characteristics to the product, inexistent in products coming from other territories[394], a decision of the Court of Justice in 1992[395] undermined this

---

391 For the interpretation of such a concept under the consumer's point of view, see K. G. GRUNERT, *Food quality and safety: consumer perception and demand*, European Review of Agricultural Economics vol. 32, 2005, pp. 369-391.

392 On this topic, see the press release of the European Commission of August 28th 2003 titled *WTO talks: EU steps up bid for better protection of regional quality products*, as well as M. FERRARI, *supra*, p. 60 and Council Regulation (EC) No 510/2006 of 20 March 2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs, whose third whereas is quoted: *"A constantly increasing number of consumers attach greater importance to the quality of foodstuffs in their diet rather than to quantity. This quest for specific products generates a demand for agricultural products or foodstuffs with an identifiable geographical origin."*

393 See also the final report of the *Advisory Group International Aspect of Agriculture*, titled *"DG AGRI working document on international protection of EU Geographical Indications: objectives, outcome and challenges"*, released after the meeting of June 25th 2012.

394 M. FERRARI, U. IZZO, *supra*, pp. 86-87.

already creaking assumption.

In fact, in the so-called Nougat of Alicante case[396], the European court, rejecting the Commission's thesis, stated that the above mentioned protection existed even though none of the product features derived from the geographical origin of the product.[397]

The gradual expansion of the scope of geographical indications protection did not stop, since in the subsequent Green Paper on agricultural product quality the Commission further extended the concept of quality, embracing all the cases where consumer expectations are met.[398]

It has to be underlined how the reference to the concept of quality within the European system of geographical indications has changed, passing from an approach focused on scientific detectability of the *quid pluris* conferred by production area, to a greater consideration of those aspects which go beyond the mere organoleptic characteristics of the product.[399]

---

[395] Judgment of the Court of 10 November 1992, Exportur SA v LOR SA and Confiserie du Tech SA (cause C-3/91).

[396] Nougat of Alicante is a renowned candy produced both in Spain and France. On June 27th 1973 a special agreement between these two countries had reserved the use of this denomination only to the Spanish products. A Spanish producer applied to the court in order to enforce the convention, so the French Court of Appeal asked the Court of Justice to address the issue of the consistence of such an agreement with the European law.

[397] Here is a pace of the decision: *"The Commission's position, which is in line with that of LOR and Confiserie du Tech, cannot be accepted. It would have the effect of depriving of all protection geographical names used for products which cannot be shown to derive a particular flavour from the land and which have not been produced in accordance with quality requirements and manufacturing standards laid down by an act of public authority, such names being commonly known as indications of provenance. Such names may nevertheless enjoy a high reputation amongst consumers and constitute for producers established in the places to which they refer an essential means of attracting custom. They are therefore entitled to protection."*
Such an approach was subsequently confirmed even in the so-called Budweiser case: see Judgment of the Court of 18 November 2003, Budéjovický Budvar, národní podnik v Rudolf Ammersin GmbH (case C-216/01).

[398] COM(2008) 641 final, Green Paper on agricultural product quality: product standards, farming requirements and quality schemes, October 15th 2008. Here is an excerpt of the text: *"Quality is about meeting consumer expectations. The agricultural product qualities addressed in this Green Paper are the product characteristics, such as farming methods used, place of farming, etc., that a farmer wants to be better known and a consumer wants to know."*

[399] To go further on the quality component of product protected under geographical indications, see also M. DESQUILBET, S. MONIER-DILHAN, *Are geographical*

Coming to the milestones that contributed to shaping the discipline of European geographical indications, here is not the case to analyze the legislative initiatives taken by individual States before the European integration process[400]; rather, it has to be considered here that first products which received such a protection were wines, which in this work are discussed under a special section.

The first regulation on the protection of the origin of agricultural and food products was set under reg. 2081/1992[401], which, in the wake of the previous regulations concerning only wine products, introduced for the first time ever in the European scene Protected Designations of Origin (PDO) and Protected Geographical Indications (PGI).[402]

This regulatory framework was subsequently replaced by reg. 510/2006[403], which, among other things, streamlined the procedure for recognition of

---

indications a worthy quality label? A framework with endogenous quality choice, Tolouse School of Economics Working Paper Series, December 2011.

[400] Above all, the French regulation of *Appellations d'origine contrôlée*, adopted by the so-called Capus law, from the name of its proponent Joseph Capus, on July 30th 1935. To go deeper, see G. DUTFIELD, *Geographical Indications and Agricultural Community development: is the European Model Appropriate for Developing Countries?*, in *"The Intellectual Property and Food Project From Rewarding Innovation and Creation to Feeding the World"*, Ashgate, January 2014, p. 179; D. GANGJEE, *Relocating the Law of Geographical Indications*, Cambridge University Press, 2012, pp. 77-114; B. O'CONNOR, *The Law of Geographical Indications*, Cameron May, 2004, pp. 165-167.

[401] It is the aforementioned Council Regulation (EEC) n. 2081/92 of 14 July 1992 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs, cited in note n. 182. Particular attention may be paid to whereas n. 3 and 9, here reported:
"Whereas, moreover, it has been observed in recent years that consumers are tending to attach greater importance to the quality of foodstuffs rather than to quantity; whereas this quest for specific products generates a growing demand for agricultural products or foodstuffs with an identifiable geographical origin; [...]
whereas the scope of this Regulation is limited to certain agricultural products and foodstuffs for which a link between product or foodstuff characteristics and geographical origin exists; whereas, however, this scope could be enlarged to encompass other products or foodstuffs."

[402] Actually, next to reg. 2081/1992, twin Council Regulation (EEC) n. 2082/92 of 14 July 1992 on certificates of specific character for agricultural products and foodstuffs mentioned also Traditional Specialities Guaranteed (TSG).

[403] It is the above mentioned Council Regulation (EC) No 510/2006 of 20 March 2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs, cited in note n. 392. At the same time, Council Regulation (EC) No 509/2006 of 20 March 2006 on agricultural products and foodstuffs as traditional specialities guaranteed reviewed the rules on TSG.

geographical indications and revised the protection system for indications coming from third countries.[404] This regulation has been recently repealed by reg. 1151/2012[405], which provides, in addition to aforementioned indications, also some optional quality terms.[406]

Coming to practical details of the European Union's protection for geographical indications, it has to be pointed out that this work will focus only on the PDO/PGI system, given its importance in both numerical and economic terms.[407]

The main differences between PDO and PGI can be found out analyzing Article 5[408] of reg. 1151/2012, which establishes requirements to be met

---

[404] Article 12.1 of reg. 2081/1992 foreseen an equivalence clause for those third countries which applied for the registration of their geographical indications in order to obtain full protection in Europe. Australia and United States asked WTO to address the issue (cases WT/DS290 and WT/DS174), and the latter considered the European provision as inconsistent with Article 3.1 of TRIPs Agreement. See also F. CATANZARO, F. LICCIARDO, *La riforma del Regolamento (CEE) 2081/92 sulla protezione delle indicazioni geografiche e delle denominazioni di origine*, in "*Agriregionieuropa*", June 2006 and M. FERRARI, *supra*, p. 59.

[405] It is the aforementioned Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs. On the impact of such a reform, see C. MACMAOLÁIN, *Food Law: European, Domestic and International Frameworks*, Bloomsbury Publishing, April 30th 2015, pp. 207-227 and V. RUBINO, *La protezione delle denominazioni geografiche dei prodotti alimentari nell'Unione europea dopo il regolamento 1151/2012*, in *"Rivista di diritto alimentare"*, 2013.

[406] They are the indications "Mountain Product" and "Product of island farming", foreseen in Articles 31-32 of reg. 1151/2012.

[407] Currently 599 PDO and 653 PGI are registered, and they represent more than 96% of 1303 geographical indications nowadays protected. Only 51 are in fact the TSG utilized.

[408] In order to better understand the quality difference between the two symbols, first two subparagraph of the provisions are quoted:
"For the purpose of this Regulation, 'designation of origin' is a name which identifies a product:
(a) originating in a specific place, region or, in exceptional cases, a country;
(b) whose quality or characteristics are essentially or exclusively due to a particular geographical environment with its inherent natural and human factors; and
(c) the production steps of which all take place in the defined geographical area.
For the purpose of this Regulation, 'geographical indication' is a name which identifies a product:
(a) originating in a specific place, region or country;
(b) whose given quality, reputation or other characteristic is essentially attributable to its geographical origin; and
(c) at least one of the production steps of which take place in the defined geographical area.

for a product to obtain such a protection.

Basically, PDO expresses a more pronounced connection with the territory of origin than PGI, especially considering that only in the first case all the production phases must take place in such an area, while in the case of PGI products even a single stage is sufficient.[409]

However, this distinction, which moreover is not always perceived by the consumer, even due to the similarity between the European symbols for PDO and PGI[410], was not considered sufficient by the lawmaker to justify a separate registration process: the latter is in fact regulated as a whole within reg. 1151/2012 and mainly consists of two phases.[411]

The first step requires a group[412] or, in some special cases, an individual producer[413] to submit an application for registration to the competent state authority. In this phase it takes place an assessment on the requirements, on the absence of impediments to registration and on the eventual oppositions. If no obstacles to the prosecution of the process, the Member State shall ensure the publication of the product specification and forward the case to the Commission.

The second phase begins when the Commission has received the applications for registration from Member States. Within six months, it must review the dossiers in order to asseverate compliance with the requirements: if this second test is positive too, the single document and the reference to the publication of the product specification shall be

---

[409] To go further on this comparison, see M. FERRARI, *supra,* pp. 65-66. It has to be considered since now that the European distinction between denominations of origin and geographical indications has not many examples in the comparative landscape.

[410] See Articles 12 and 44 of reg. 1151/2012.

[411] *Ibid.,* Articles 48 et seq. Also TSG follow the same procedure.

[412] The groups admitted to submit a registration application are those which work with the products whose indication to be registered. On the extension of the meaning of verb "work", see M. FERRARI, *supra,* p. 67 note n. 100.

[413] Such an exception is permitted where the referred zone is particularly different from those neighbouring and the person is the only producer who want to obtain the registration. It can be a natural person as well as a legal person, as stated in Article 49 of reg. 1151/2012. Anyway, the most of indications is registered by groups.

published in the Official Journal of the European Union (OJEU).[414]

The geographical indication is definitively registered if, within three months after the publication, no oppositions are submitted at the European level, or, if submitted, where they end with an agreement between proponent and opponent.[415]

The European Union, in order to grant a greater accessibility to the category of protected indications, has created a special register, the so-called DOOR[416], containing a list of all the registered geographical indications or pending examination by the institutions, including also those of third countries.

It has to be underlined here the special feature of European Union's geographical indications: far from being owned by individual producers, as in the case of ordinary trademarks, they present instead a strong collective nature.

In fact, although following individual applications, PDO and PGI are effectively approved after a public procedure which verifies the presence of a series of parameters expressly required by European regulation; and, even after their registration, they cannot be owned by anyone, but can be adopted by any producer who complies with the single product specification, which in fact represents the core element of the indication.[417]

These peculiarities emerge with greater clarity when considering the provisions of reg. 1151/2012 with regard to their relation with trademarks: as a matter of fact, while the registration of a PDO or PGI conflicting with a pre-existing mark is precluded only where the latter has acquired reputation over time and the consumers may be misled[418], it is

---

[414] See Article 50, reg. 1151/2012.

[415] *Ibid.*, Article 52.

[416] *Database of Origin and Registration,* available at http://ec.europa.eu/agriculture/quality/door.

[417] On the nature of the European geographical indications, see in depth M. FERRARI, U. IZZO, *supra,* pp. 102-103.

[418] See Article 6 of reg. 1151/2012. Where this double requirement is not satisfied it is established a coexistence regime between the mark, which may be further used,

not possible instead to register a trademark which conflicts with an earlier PDO or PGI even due to mere indirect recalls to the indication or similarity between products.[419]

This represents not only the different nature of geographical indications compared to marks, but also the general favor of the European lawmaker for the first institute.

Such a detailed system, exclusively referred to geographical indications of food and agricultural products, cannot be found in the United States, where in fact an analogous institute has never been foreseen, rather opting for the adaptation of existing legal tools.

First of all, geographical indications may be protected in the American territory even without registration, through the remedies provided by common law.[420] Nevertheless, such a kind of protection heavily lacks under the aspect of ownership presumption and use with third countries.[421]

For this reason, the most common tools are certification marks and collective marks[422], as regulated under Lanham Act[423], which is the basic

---

and the geographical indication, which may be registered. See also M. FERRARI, *supra*, p. 75.

419 *Ibid.*, Article 14.

420 See for instance the Cognac case, contained in the decision Institut National Des Appellations v. Brown-Forman Corp., 47 U.S.P.Q.2d 1875 (1998).

421 See particularly L. BERESFORD, *Geographical Indications: The Current Landscape*, in *"Fordham Intellectual Property, Media and Entertainment Law Journal"*, vol. 17, 2007, p. 982.

422 The two marks are regulated under 15 USC, section 1054. The following section 1127 underlines the differences between the marks. An excerpt of the latter is cited: *"The term "certification mark" means any word, name, symbol, or device, or any combination thereof-*
(1) used by a person other than its owner, or
(2) which its owner has a bona fide intention to permit a person other than the owner to use in commerce and files an application to register on the principal register established by this chapter,
to certify regional or other origin, material, mode of manufacture, quality, accuracy, or other characteristics of such person's goods or services or that the work or labor on the goods or services was performed by members of a union or other organization.
The term "collective mark" means a trademark or service mark-
(1) used by the members of a cooperative, an association, or other collective group or organization, or
(2) which such cooperative, association, or other collective group or organization

statute considered in the following lines. A particular option, quite rare, consists in protecting the indication as an ordinary trademark, where it has acquired a secondary meaning.[424]

Certification marks are probably the closest institute to European geographical indications system: indeed, they are owned by bodies others than the producer and appear to be more committed to underlining the qualities of the product which they refer to.[425] Nonetheless, it is not mandatory for these marks to express a link between the place of origin and a particular quality.[426]

The fact that the owner of the mark is an entity other than the producer allows products of the latter which contain such a mark to be effectively and independently certified.

Concerning instead collective marks, they appear to be slightly more different from the European concept of geographical indication. First, here the separation between sign's owner and its effective user is not ensured, differently from the case of certification marks[427]; but above all it is not mandatory to refer to the region of production or to product qualities and characteristics.

This leads to consider the collective mark as a mere symbol which identifies that a certain good belongs to a certain organization, whose

---

has a bona fide intention to use in commerce and applies to register on the principal register established by this chapter,
and includes marks indicating membership in a union, an association, or other organization."

[423] It is the Trademark Act. An Act to provide for the registration and protection of trade-marks used in commerce, to carry out the provisions of certain international conventions, and for other purposes of July 5th 1946, which take the name from the Texan MP who proposed it, Fritz G. Lanham. This statute was codified as 15 USC and has been deeply amended by the reform of Trademark Counterfeiting Act in 1984.

[424] On this point, see L. BERESFORD, *supra*, pp. 984-985.

[425] On the topic, see particularly M. A. ECHOLS, *Geographical Indications for Food Products: International Legal and Regulatory Perspectives*, Kluwer Law International, 2008, pp. 137-144.

[426] On this point, see M. FERRARI, *supra*, p. 54.

[427] In the sense that the owner is the group or the association and the use is reserved to relative members. On this point, see E. K. MELTZER, *"Pass the Parmesan? What you need to know about Geographical Indications and Trademarks"*, in *"Virginia Lawyer"*, June 2002, p. 20.

reputation is leveraged in order to guarantee the consumer.

Finally, it has been mentioned before the possibility, actually very rare, to protect geographical indications through normal trademarks, without falling under the prohibition of registration for names corresponding to geographical regions.[428]

This may happen where, following the protract use of a sign as an indication of origin of the product, consumers begin to assign an ulterior meaning to the mark, as a reference for a certain producer or group of producers: in this case, such a secondary meaning may be protected as a trademark.[429]

Regarding instead the registration procedure, it follows the ordinary process used for marks, except for the absence of specific requirements set with regard to collective marks and to certification marks.

The applications has to be submitted to the United States Patent and Trademark Office (USPTO), which however does not draw up a list of the registered geographical indications, so currently is not possible to see the full picture of those marks - *in primis*, certification marks - which are used for such purposes.[430]

Similarly to the European regulation, even under the American rules it is possible to initiate an opposition procedure, as well as to register marks of third countries.[431]

---

[428] The prohibition to register geographical names is justified by the protection of consumers, otherwise misled with regard to the origin of the product. On this topic, see M. A. ECHOLS, *Geographical Indications for Food Products: International Legal and Regulatory Perspectives*, Kluwer Law International, 2008, pp. 144-147 and L. BERESFORD, *supra*, pp. 984-985.

[429] On this point, see S. AGARWAL, M. J. BARONE, *Emerging Issues for Geographical Indication Branding Strategies*, MATRIC Research Papers, January 2005.

[430] See E. BARHAM, J. BINGEN, C. C. HINRICHS, *Geographical Indications in the USA*, in *"Labels of origin for food: local development, global recognition"*, CAB International, May 27th 2011, p. 125 and D. GIOVANNUCCI, T. JOSLING, W. KERR, B. O'CONNOR, M. T. YEUNG, *Guide to Geographical Indications linking products and their origins*, International Trade Center, 2009, pp. 64-65.

[431] See also B. O'CONNOR, *Indicazioni Geografiche: alcune riflessioni sulla prassi dell'Ufficio Marchio e Brevetti degli Stati Uniti e l'accordo TRIPs*, in *"Rivista di diritto alimentare"*, October 2013, as well as the report funded by the Commission

It is evident, thus, that conditions for the establishment of a proper specific protection system for geographical indications have never occurred in the United States. In particular, it does not seem that the link with the production area represents, within the American market, a very prominent element for the global quality of foods, as it seems to be diffusely perceived by European consumers.[432]

2. THE INTERNATIONAL FRAMEWORK

In addition to the national provisions above mentioned, there are also some international agreements which regulate on geographical indications. In this sense, both the European Union and the United State must always comply with the rules of international regulatory framework.

The most dated[433] is certainly the Madrid Agreement of 1891[434], under which eight States[435] tried to adopt the first countermeasures against products with false or misleading appellations of origin.[436]

---

titled *"Geographical indications and TRIPs: 10 Years Later... A roadmap for EU GI holders to get protection in other WTO Members"*, of June 2007.

[432] On the consumers' preferences on geographical indications, see L. MENAPACE, G. COLSON, C. GREBITUS, M. FACENDOLA, *Consumer preferences for country-of-origin, geographical indication, and protected designation of origin labels*, Iowa State University, November 2009.

[433] Actually, the very first regulatory text is represented by the Paris Convention for the Protection of Industrial Property of March 20th 1883, whose Articles 15 and 16 are mentioned by the following Madrid Agreement.

[434] Madrid Agreement Concerning the International Registration of Marks, April 14th 1891. Next to this treaty it was signed also a Protocol Relating to the Madrid Agreement, which entered in force five years later. Both the texts have been amended over years and currently they compose the so-called Madrid system.

[435] Nine, considering separately France and Tunisia. The other parts were Belgium, Spain, Switzerland, Italy, Guatemala, Netherlands and Portugal. Nowadays this treaty has been signed by 55 countries, among which 19 are Member States of the European Union. However, such a list does not include the United States, which, taking part of only the Protocol since 2003, just appear in the Assembly of the treaty, which collects 96 States.

[436] Here is the text of Article 1 of the Agreement: *"Les sujets ou citoyens de chacun des Etats contractants pourronts'assurer, dans tous les autres Etats, la protection de leurs marques de fabrique ou de commerce acceptees au depot dans le pays d'origine, moyennant le depot desdites marques au Bureau international, a Berne,*

However, the first proper protection for geographical indication was established only with the subsequent Lisbon Agreement of 1958[437], which provided with the first definition of appellation of origin[438], intensifying its protection.[439] The signatory countries however retained the possibility to notify, with a reasoned statement, not to be able to grant protection to particular denominations.[440]

Among the innovations of the Agreement, it was established a special bulletin[441] which recollected all the registered indications protected under the considered system.

The wider protection ensured to denominations of origin surely has not contributed to the success of the treaty, which remains confined to a small number of accessions: even for this reason, recently it has been perceived the need to enter in a process which may lead to reforming the Lisbon

---

fait par l'entremise de I' Administration dudit pays d'origine." See also M. FERRARI, U. IZZO, *supra,* p. 116.

437 Lisbon Agreement for the Protection of Appellations of Origin and their International Registration, October 31st 1958. The text was amended in 1967 and 1979 and it is currently in force between only 28 States, among which there is not the United State.

438 The original content, currently unchanged, of Article 2 is here cited: *"On entend par appellation d'origine, au sens du présent Arrangement, la dénomination géographique d'un pays, d'une région ou d'une localité servant à désigner un produit qui en est originaire et dont la qualité ou les caractères sont dus exclusivement ou essentiellement au milieu géographique, comprenant les facteurs naturels et les facteurs humains.*
Le pays d'origine est celui dont le nom, ou dans lequel est situé la région ou la localité dont le nom, constitue l'appellation d'origine qui a donné au produit sa notoriété."

439 *Ibid.*, Article 3: *"La protection sera assurée contre toute usurpation ou imitation, même si l'origine véritable du produit est indiquée ou si l'appellation est employée en traduction ou accompagnée d'expressions telles que "genre", "type", "façon", "imitation" ou similaires."*

440 *Ibid.*, Article 5.3: *"Les Administrations des pays pourront déclarer qu'elles ne peuvent assurer la protection d'une appellation d'origine, dont l'enregistrement leur aura été notifié, mais pour autant seulement que leur déclaration soit notifiée au Bureau international, avec l'indication des motifs, dans un délai d'une année à compter de la réception de la notification de l'enregistrement, et sans que cette déclaration puisse porter préjudice, dans le pays en cause, aux autres formes de protection de l'appellation auxquelles le titulaire de celle-ci pourrait pretender, conformément à l'article 4 ci-dessus."*

441 Such a bulletin is available at the page www.wipo.int/lisbon/en/bulletin and is expressly foreseen by Article 5.2 of the treaty: *"Le Bureau international notifiera sans retard les enregistrements aux Administrations des divers pays de l'Union particulière et les publiera dans un recueil périodique."*

Agreement.[442] This series of meetings has brought in May 2015 to the Geneva Act[443], which nevertheless does not appear to sort huge effects.

A possible solution may consist in a special Protocol[444], similar to the Madrid Agreement's one, which through less strict provisions may concur to attract the consensus of the most skeptical countries.[445]

It has to be underlined that both the Madrid Agreement and the Lisbon Agreement are administered by the World Intellectual Property Organization (WIPO)[446], the agency of the United Nations committed to promoting the protection of intellectual property around the world.

In addition to such a regulatory framework it has to be considered even what is foreseen by the aforementioned TRIPs Agreement, signed among WTO after the Uruguay Round.[447]

As will be better highlighted in the following pages, this treaty established a different level of protection for general geographical indications and for those related to wine and spirits. This is mainly due to the compromise solution[448] laboriously found between the position of those States,

---

[442] On the Lisbon Agreement reformation process, see above all D. J. GERVAIS, *Reinventing Lisbon: The Case for a Protocol to the Lisbon Agreement (Geographical Indications)*, Chicago Journal of International Law, June 2010.

[443] Geneva Act of the Lisbon Agreement on Appellations of Origin and Geographical Indications, May 20th 2015. Up to now the text has collected only 14 accessions.

[444] D. J. GERVAIS, *supra*, pp. 121-124. Here is a pace of the text: *"A protocol to the Lisbon Agreement would allow WTO Members to keep the advantages of the Lisbon system (expertise, registration system refusals) while removing (for parties to the protocol, not the Agreement) irritants such as the rule against genericide and allow WTO Members to use-and perhaps tweak-TRIPS rules concerning conflicts between trademarks and GIs."*

[445] Among them, the United States are strongly against to provisions which may impede the supervening genericity of denominations as stated in Article 6 of Lisbon Agreement: *"An appellation which has been granted protection in one of the countries of the Special Union pursuant to the procedure under Article 5 cannot, in that country, be deemed to have become generic, as long as it is protected as an appellation of origin in the country of origin."*

[446] The organization was established on July 14th 1967 due to the signature of the Convention Establishing the World Intellectual Property Organization in Stockholm.

[447] On this topic, see also D. GIOVANNUCCI, T. JOSLING, W. KERR, B. O'CONNOR, M. T. YEUNG, *supra*, pp. 41-42.

[448] See C. E. HANRAHAN, *Geographical Indications and WTO Negotiations*, Congressional Research Service, July 14th 2003, pp. 2-3.

European Union *in primis*, which asked for a protection level at least equal to that foreseen by Lisbon Agreement[449], and the position of other States, like United States and Canada, which preferred a less restrictive solution, with a protection similar to the certification marks' one.[450]

It is sufficient here to consider that, concerning the case of geographical indications[451], Article 22 sets a standard protection aimed at impeding the registration of marks which contain a geographical indication, other than the real production region, only when it can be demonstrated that they may mislead consumers with regard to the place of origin of the product.[452]

It is, actually, a very burdensome requirement to comply with, especially considering that, differently from the case of wine products, there are not special rules which may prevent the insertion of the real region of origin next to the denomination or the use of words as "like" or "style", or, moreover, the use of translations of protected indications.

Therefore, it is easily understandable why the position of the United States is currently focused in trying to reach an agreement which may not differ so much from the provisions of Article 22 of TRIPs, while the efforts of European Union are committed to defending at least the contents of the Lisbon Agreement, asking to converge on similar positions even countries, as the United States, which are not part of such a system.

---

[449] See also the position expressed by the European Community in the Draft agreement on trade-related aspects of intellectual property rights (MTN.GNG/NG11/W/68) of March 29th 1990.

[450] See also the position expressed by the United States in the Draft agreement on trade-related aspects of intellectual property rights (MTN.GNG/NG11/W/70) of May 1st 1990.

[451] Geographical indications are defined by Article 22.1 of the Agreement as *"[...] indications which identify a good as originating in the territory of a Member, or a region or locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin."*

[452] *Ibid.*, Article 22.3: *"A Member shall, ex officio if its legislation so permits or at the request of an interested party, refuse or invalidate the registration of a trademark which contains or consists of a geographical indication with respect to goods not originating in the territory indicated, if use of the indication in the trademark for such goods in that Member is of such a nature as to mislead the public as to the true place of origin."*

3. THE ENHANCED PROTECTION OF WINE PRODUCTS

While the provisions of Article 22 of TRIPs Agreement was a kind of victory for the American negotiators involved in the Uruguay Round, the protection provided for wine products by the following Article 23 was instead significantly closer to the expectations of European representatives.[453]

Working as a reinforced protection compared to the standard just above mentioned, the rules set for geographical indications of wine products appear to rectify the shortcomings of the general provision: in fact, not only it is not required to demonstrate the risk of confusion for consumers on the real region of origin of the product, but it is also prohibited to use terms as "like" or "style" or translations of the protected denomination or, moreover, the insertion of the real production zone next to the indication.[454]

Moreover, aiming to facilitate cooperation between signatories, Article 23 provided also a dialogue to be started within TRIPs Council in order to establish a unique registration system for wine products geographical indications.[455]

---

[453] It is evident that such a treatment disparity has its roots in historical (wine sector has been a real training ground for growing geographical indications as a legal institute), economic (wine products has an enormous value within the international market) and organoleptic reasons (as a matter of fact, it is generally recognized the influence of the ecosystem of the production zone on the final characteristic of wine products). On this point, see also M. FERRARI, U. IZZO, *supra*, p. 118; E. BARHAM, J. BINGEN, C. C. HINRICHS, *supra*, p. 123; M. FERRARI, *supra*, p. 97.

[454] Here is the text of Article 23.1: *"Each Member shall provide the legal means for interested parties to prevent use of a geographical indication identifying wines for wines not originating in the place indicated by the geographical indication in question or identifying spirits for spirits not originating in the place indicated by the geographical indication in question, even where the true origin of the goods is indicated or the geographical indication is used in translation or accompanied by expressions such as "kind", "type", "style", "imitation" or the like."* See also diffusely C. E. HANRAHAN, *supra*.

[455] Here is the text of Article 23.4: "*In order to facilitate the protection of geographical indications for wines, negotiations shall be undertaken in the Council for TRIPS concerning the establishment of a multilateral system of*

In order to comply with such international provisions, the American system raises the level and the quality of the legal response, even considering the increasing importance which wine products have assumed during time, with regard to both domestic and international markets.[456]

The reference is represented by two provisions of Code of Federal Regulation, which, although with different aims, rule on wine geographical indications.[457]

On one side, the Alcohol and Tobacco Tax and Trade Bureau (TTB)[458] is supposed to distinguish, case by case, among generic geographical names[459], semi-generic geographical names[460] and non-generic geographical

---

notification and registration of geographical indications for wines eligible for protection in those Members participating in the system." Nonetheless, such a system has never been implemented. On this point, see D. GAETA, P. CORSINOVI, *Traditional Terms and Appellation wines: debates insight of TTIP negotiation,* 145th EAAE Seminar, April 2015, p. 5.

[456] On this point, see deeply J. T. LAPSLEY, *Bottled Poetry: Napa Winemaking from Prohibition to the Modern Era*, University of California Press, 1996 and R. JOHNSON, J. BRUWER, *Regional brand image and perceived wine quality: the consumer perspective*, International Journal of Wine Business Research, vol. 19, 2007, pp. 276-297.

[457] See 17 CFR, Parts 4.24 and 4.25. While in the first case the *ratio* of the rule concerns the possibility for American producers to use denominations which refer to foreign geographical areas, the second case is an attempt to create a system of denomination of origin. See also M. FERRARI, *supra*, p. 109, note n. 42.

[458] Alcohol and Tobacco Tax and Trade Bureau (TTB) is part of the U.S. Department of Justice. On the particular choice to provide such an agency with the power to regulate on geographical indications, see E. BARHAM, J. BINGEN, C. C. HINRICHS, *supra*, p. 123.

[459] 17 CFR, Part 4.24(a): *"A name of geographic significance which is also the designation of a class or type of wine, shall be deemed to have become generic only if so found by the Administrator.*
Examples of generic names, originally having geographic significance, which are designations for a class or type of wine are: Vermouth, Sake."

[460] *Ibid.*, Part 4.24(b): *"A name of geographic significance, which is also the designation of a class or type of wine, shall be deemed to have become semi-generic only if so found by the Administrator. Semi-generic designations may be used to designate wines of an origin other than that indicated by such name only if there appears in direct conjunction therewith an appropriate appellation of origin disclosing the true place of origin of the wine, and if the wine so designated conforms to the standard of identity, if any, for such wine contained in the regulations in this part or, if there be no such standard, to the trade understanding of such class or type. [...]*
Examples of semi-generic names which are also type designations for grape wines are Angelica, Burgundy, Claret, Chablis, Champagne, Chianti, Malaga, Marsala, Madeira, Moselle, Port, Rhine Wine (syn. Hock), Sauterne, Haut Sauterne, Sherry, Tokay."

names[461], adopting a different legal treatment for each of them: while the firsts are freely available, the latters may be used even for products coming from zones which differ from those included in the denomination, provided that the real origin is indicated. With reference to non-generic geographical names, finally, they may be used only for those wines which effectively originate from such a region; however, they are considered as a proper denomination of origin only where there is such a perception among consumers.[462]

On the other side, the same office is committed to supervising on a series of appellations of origin for wine products. They are probably the closest American legal tool to the geographical indications system established within the European Union.[463]

Such denominations may coincide, with different constraints on production process depending on the extension of selected area[464], with the entire territory of United States, with one, two or three of its States[465], with one, two or three counties of the same State or, at last, with a viticultural area. The same partition, *mutatis mutandis*, may be applied in case of denominations of imported products.

---

[461] *Ibid.*, Part 4.24(c)(1): *"A name of geographic significance, which has not been found by the Administrator to be generic or semi-generic may be used only to designate wines of the origin indicated by such name, but such name shall not be deemed to be the distinctive designation of a wine unless the Administrator finds that it is known to the consumer and to the trade as the designation of a specific wine of a particular place or region, distinguishable from all other wines."*

[462] This corresponds to the distinction between distinctive and non-distinctive non-generic geographical names.

[463] On this point, see M. FERRARI, *supra*, p. 110; T. ATKINS, R. JOHNSON, *Appellation as an indicator of quality*, International Journal of Wine Business Research, vol. 22, 2007, pp. 42-61; M. CANAVARI, N. CANTORE, A. CASTELLINI, E. PIGNATTI, R. SPADONI, *International marketing and trade of quality food products*, Wageningen Academic Publishers, 2009; R. MENDELSON, *From demon to darling: a legal history of wine in America*, University of California Press, 2009, pp. 141-158.

[464] Where the denomination coincides with the United States or a State or a county at least 75% of wine must be produced with grapes originating from such a region: instead, where the denomination refers to more counties or more States, all the grapes must derive from such a zone. See 17 CFR, Part 4.35.

[465] States must be neighbors.

Among these denominations, those related to a viticultural area are subjected to a strict regulation, which however enhance the qualities of products. It has to be taken into account since now that where such an area insists on the American territory it may be referred to American Viticultural Area (AVA).[466]

This particular kind of appellations of origin undergoes, differently from the other denominations, to a prior authorizing procedure administered by TTB which is very similar to that regarding PDO and PGI[467], especially considering that the individual admitted to submit an application may not acquire any sort of ownership with reference to the AVA, when it approved. In fact, it has a different and separate legal nature than the common American certification mark's one, and it may easily coexist with the latter.[468]

Moreover, not only it is required a higher quantity of grapes originating from the selected area compared to other kinds of denominations[469], but under the authorizing application it is also necessary to underline the distinguishing features of the area, the grapes and the product which confer originality to the wine itself.[470]

---

[466] AVAs are regulated under 17 CFR, Part 9.

[467] Not only there are proper opposition procedures after the publication of the proposal for the authorization in the Federal Register, but the AVA authorization itself depends also on the effective enactment of the subsequent regulation by TTB.

[468] On this point, see M. FERRARI, *supra*, pp. 114-115.

[469] At least 85% of used grapes must originate from the selected viticultural area. See 17 CFR, Part 4.25(e)(3)(ii).

[470] *Ibid.*, Part 9.12(a)(3): *"The petition must provide, in narrative form, a description of the common or similar features of the proposed AVA affecting viticulture that make it distinctive. The petition must also explain with specificity in what way these features affect viticulture and how they are distinguished viticulturally from features associated with adjacent areas outside the proposed AVA boundary. For purposes of this section, information relating to distinguishing features affecting viticulture includes the following:*
(i) Climate. Temperature, precipitation, wind, fog, solar orientation and radiation, and other climate information;
(ii) Geology. Underlying formations, landforms, and such geophysical events as earthquakes, eruptions, and major floods;
(iii) Soils. Soil series or phases of a soil series, denoting parent material, texture, slope, permeability, soil reaction, drainage, and fertility;
(iv) Physical features. Flat, hilly, or mountainous topography, geographical

The peculiarity of American regulation on geographical indications in wine sector is instead almost absent in Europe, where however the regulatory framework of food and agricultural products remains at a higher level of protection than that foreseen under both the aforementioned provisions of TRIPs Agreement.

Nevertheless, even the European Union is not indifferent to the historical and economic issues[471] of wine sector.

Actually, looking deeper, the system of PDO and PGI may seem not to cover also wines, which in the past were in fact regulated by reg. 479/2008[472], whose provisions have been then included within reg. 1234/2007[473], according to the creation of the so-called single CMO.[474]

Nowadays, this field is regulated by recent reg. 1308/2013[475], which, despite some relevant differences, as a deeper level of detail in specifying some requisites and procedural requirements as well as an equalization of criteria set for the denominations[476], establishes *de facto* a similar system to that foreseen by reg. 1151/2012, maintaining in fact the names PDO and PGI.

---

formations, bodies of water, watersheds, irrigation resources, and other physical features; and
(v) Elevation. Minimum and maximum elevations."

[471] See note n. 453.

[472] Council Regulation (EC) No 479/2008 of 29 April 2008 on the common organisation of the market in wine, amending Regulations (EC) No 1493/1999, (EC) No 1782/2003, (EC) No 1290/2005, (EC) No 3/2008 and repealing Regulations (EEC) No 2392/86 and (EC) No 1493/1999.

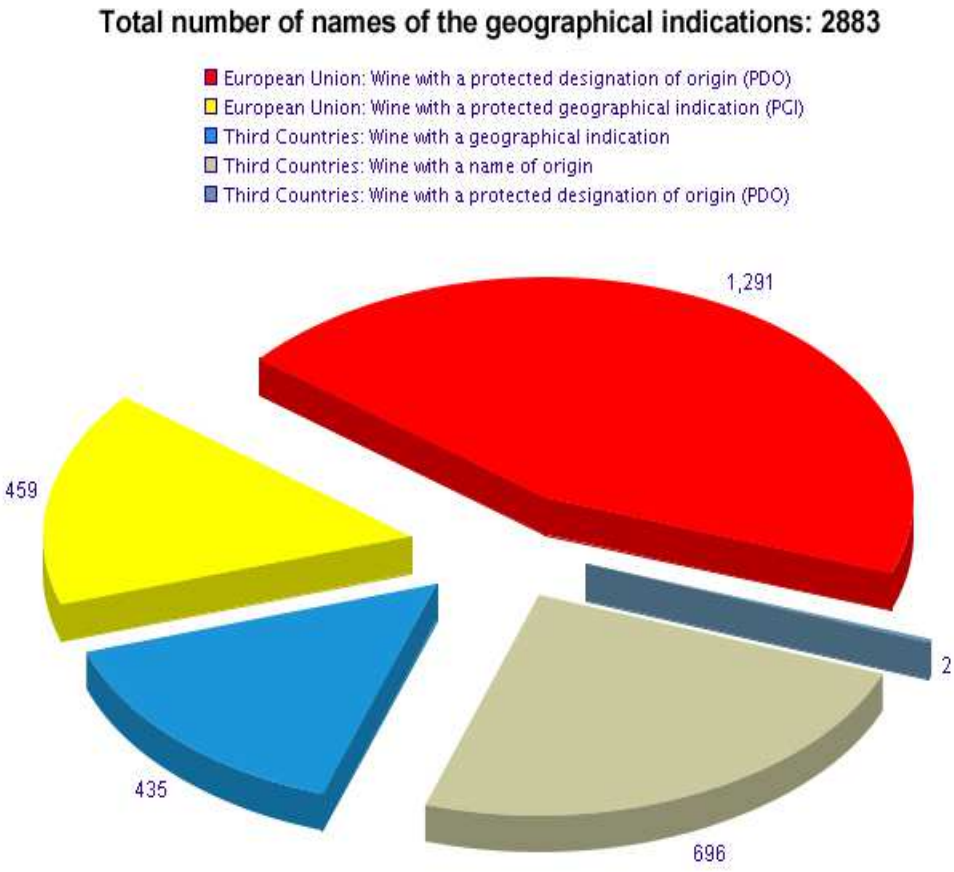
[473] Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation).

[474] The matter of Common Market Organization (CMO) may per se deserve a deep focus, but this is note the purpose of this work. It has just to be considered that CMOs has been the legal tool adopted by the European Community under the Common Agricultural Policy (CAP). Arisen after the Stresa Intergovernmental Conference of 1958, they had been representing during years the main regulations on a series of food and agricultural production typologies, until they were reorganized under the so-called single CMO by reg. 1234/2007.

[475] Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007.

[476] Both PDO and PGI require completing all the production phases within the selected area.

From a practical perspective, it is useful to underline that PDO and PGI of wine products are recollected in a special register called E-BACCHUS[477], which contains also indications from third countries.
To better understand the importance, even merely numerical, of PDO and PGI wine products within the international market, see the chart on this page.[478]



[477] Such a register, established under Article 104 of reg. 1308/2013, is available at the address http://ec.europa.eu/agriculture/markets/wine/e-bacchus. Similarly, for the spirits is in force the register E-SPIRIT-DRINKS, established under Article 15 and Annex III of Regulation (EC) No 110/2008 of the European Parliament and of the Council of 15 January 2008 on the definition, description, presentation, labelling and the protection of geographical indications of spirit drinks and repealing Council Regulation (EEC) No 1576/89, available at the address http://ec.europa.eu/agriculture/spirits.

[478] Such a chart is available on the official site of E-BACCHUS register.

Recently, United States and European Union have signed an important bilateral agreement aimed at solving some issues related to wine products trade across the Atlantic Ocean.[479]

It is the Wine Trade Agreement[480], concluded in 2006 after a long negotiating period and importing a series of innovations, among which the recognition of each other's winemaking practices[481] and of some both parties' denominations of origin.[482]

The most important point to underline is the fact that such an agreement affected the treatment of some European denominations under the American regulatory framework: as a matter of fact, with reference to 17 particularly renowned wines[483], very prominent for global trade, the United States agreed to limit the use of related denomination only to those products effectively originating in the selected European regions.[484]

However, the effectiveness of such a provision is mitigated by the presence of a grandfathering clause[485] which permits the usage of such

---

[479] On this point, see B. ROSE, *No More Whining About Geographical Indications: Assessing the 2005 Agreement Between the United States and the European Community on the Trade in Wine*, Houston Journal of International Law, 2007, pp. 759-770.

[480] Agreement between the European Community and the United States of America on trade in wine, London, March 10th 2006.

[481] One of the main obstacles to transatlantic trade was the fact that, on one hand, the European Union did not allow to add acid solutions in order to balance those wines produced with very ripened grapes (which was instead a common practice for American producers), while the United States was strongly skeptical on the sugar addition of European wines.

[482] See Annexes IV and V of the Agreement.

[483] They are: Burgundy, Chablis, Champagne, Chianti, Claret, Haut Sauterne, Hock, Madeira, Malaga, Marsala, Moselle, Port, Retsina, Rhine, Sauterne, Sherry e Tokay. See Annex II of the Agreement. The rest of the names fall under the provision of Article 7, which states:

[484] *Ibid.*, Article 6.1: *"With respect to wine that is sold in the territory of the United States, the United States shall seek to change the legal status of the terms in Annex II to restrict the use of the terms on wine labels solely to wine originating in the Community. Labels for such wines may use the terms in Annex II in a manner consistent with the US wine labelling regulations in force as of 14 September 2005."*

[485] *Ibid.*, Article 6.2: *"Paragraph 1 shall not apply with respect to any person or its successor in interest using a term listed in Annex II on a label of a wine not originating in the Community, where such use has occurred in the United States before 13 December 2005, or the date of signature of this Agreement, whichever is*

names to producers who utilized them before the entry into force of the Agreement.[486]

4. NO REVOLUTIONS: SOME DOWN TO EARTH SOLUTIONS

The strong differences between the European protection system of geographical indications and its almost complete absence within the United States do not certainly seem to be the prelude to a revolution in the policies of both the parties in this field.

Nevertheless, it does not mean that there are not spaces and political margins to find a compromise solution which may satisfy both the superpowers involved in TTIP negotiation.

It appears, however, as particularly evident that a solution under WTO is unattainable by this time, thus especially the European Union preferred to start focusing on the conclusion of bilateral agreements with individual third countries.[487]

Actually, the progressive sinking of Doha Development Round has certified the impossibility of creating a single strong regulatory framework concerning geographical indications.[488] The mandate[489] of such a series of meetings focused indeed on two main points: on one side, a multilateral

---

later; provided that the term may only be used on labels for wine bearing the brand name, or the brand name and the fanciful name, if any, for which the applicable COLA was issued prior to the later date referred to in this paragraph and the term is presented on the label in accordance with the regulations in effect on 14 September 2005."

[486] More precisely, before December 13th 2005. Globally, see also E. M. APPIANO, S. DINDO, *Le pratiche enologiche e la tutela delle denominazioni d`origine nell`Accordo UE/USA sul commercio del vino*, in *"Contratti e Impresa - Europa"* vol. 1, 2007, pp. 496-500.

[487] For a view of the several concluded agreements or still under negotiation, see the press release of the Commission of August 1st 2013, titled *"The EU's bilateral trade and investment agreements – where are we?"*

[488] For a further focus on the Doha Development Round in matter of geographical indications, see G. E. EVANS, M. BLAKENEY, *The Protection of Geographical Indications After Doha: Quo Vadis?*, Journal Of International Economic Law, September 2006, pp. 603-614.

[489] WTO Doha Ministerial declaration WT/MIN(01)/DEC/1 adopted on 14 November 2001.

register for wine products should have been established; on the other side, it was taken into consideration the possibility to extend the reinforced protection of Article 23 TRIPs also to other products.[490]

As regards the first aspect, following the emersion of a rift between those States[491] which aimed to a mandatory system and those which were more skeptical, in April 2011 the TRIPs Council released a report[492], which however had not a huge success.

Concerning, instead, the possible extension of the stronger protection also to those geographical indications related to food and agricultural products, the respective positions[493] have to be considered, if possible, as even more distant: this is testified by the fact that, after the final report of 2001[494], no further steps have been taken.

It has to be remembered as, meanwhile, the United States had reacted to the pressure of European representatives calling on WTO dispute resolution bodies in order to state on the consistence of some provisions of PDO and PGI regulation.[495]

---

[490] *Ibid.*, par. 18: *"With a view to completing the work started in the Council for Trade-Related Aspects of Intellectual Property Rights (Council for TRIPS) on the implementation of Article 23.4, we agree to negotiate the establishment of a multilateral system of notification and registration of geographical indications for wines and spirits by the Fifth Session of the Ministerial Conference. We note that issues related to the extension of the protection of geographical indications provided for in Article 23 to products other than wines and spirits will be addressed in the Council for TRIPS pursuant to paragraph 12 of this declaration."* On the nature of such a commitment, see K. M. MURPHY, *Conflict, confusion, and bias under TRIPs Articles 22-24*, American University International Law Review, 2004.

[491] See the position of the European Community in the Communication from the European Communities and their Member States (IP/C/W/107) of July 28th 1998.

[492] Report by the Chairman to the Trade Negotiations Committee (TN/IP/21) of April 21st 2011.

[493] See the Communication from the European Communities (TN/IP/W/11) of June 14th 2005 and the Communication from Albania, Brazil, China, Colombia, Ecuador, the European Communities, Iceland, India, Indonesia, the Kyrgyz Republic, Liechtenstein, the Former Yugoslav Republic of Macedonia, Pakistan, Peru, Sri Lanka, Switzerland, Thailand, Turkey, the ACP Group and the African Group (TN/C/W/52) of July 19th 2008.

[494] Cover Note by TNC Chair (TN/C/13), April 21st 2011.

[495] See note n. 404, as well as S. D. GOLDBERG, *Who Will Raise the White Flag? The Battle between the United States and the European Union over the Protection of Geographical Indications*, Journal of International Law, 2001.

For these reasons, failing in finding a global point of agreement within the international bodies, the European Union and the United States considered to start to discuss directly, under TTIP negotiations, and to conclude a series of agreements on geographical indications and, more generally, on intellectual property, with other countries. In this view, both the powers have tried to persuade the individual countries into accepting their regulatory standards and policies, aiming at the same time to politically isolate the respective transatlantic partner.[496]

Basically, the strategies adopted by United States and European Union are quite similar, even though opposite.

The high European officials have started to work on introducing, in each future trade agreement with third countries, provisions which improve the protection foreseen under TRIPs Agreement.[497]

This is what is usually called as TRIPs plus[498], whom the European Union has begun to negotiate within other bilateral treaties, focusing on some core points as the direct and unconditioned protection in the signatory State of a list of indications[499] and the extension of the protection set under Article 23 TRIPs also to food and agricultural products.

---

[496] Such a strategy is particularly important for the European Union, considering that the United States is currently by far the leading destination country for the export of products which contain geographical indications. See also the *Guide to the EU's proposal on Agriculture and Geographical Indications (GIs).*

[497] See the aforementioned *"DG AGRI working document on international protection of EU Geographical Indications: objectives, outcome and challenges"* at p. 8: *"In the new generation of FTAs a satisfactory GI Chapter is a "must have" for the EU. However it should be clear that the EU objective is not to impose a mere transposition of its internal legislation to the concerned third countries; it would not be realistic in some cases."*

[498] On the positions of the States on this topic, see J. F. MORIN, *Multilateralising TRIPS-Plus Agreements: Is the US Strategy a Failure?*, Journal of World Intellectual Property, 2009 and, more generally, H. G. RUSE-KHAN, *The International Law Relation between TRIPS and Subsequent TRIPS-Plus Free Trade Agreements: Towards Safeguarding TRIPS Flexibilities?*, Journal of Intellectual Property Law, May 19th 2011.

[499] Usually, they are the denomination with the highest economic importance on the European exports balance: on this point, see the interview to Prof. Alan Matthews in the article of January 8th 2015 in *"Borderlex"*, titled *Geographical indications in TTIP: a new European controversy*. However, often this protection has to coexist with the provision of special grandfathering clauses aimed at protecting producers who have previously used such names.

Such an approach has been followed also in the recent agreement with Canada[500], where 173 European geographical indications considered as worthy of particular protection have been inserted.[501] However, such a choice may easily contribute to the emersion of some grumbles from producers and Member States which have been excluded, increasing suggestions which confer a negative meaning to the concept of "two-speed" Europe.

On the contrary, in the United States there are strong political pressures[502] which aim to weaken the European Union's position on geographical indications protection.

The point is that, on the base of the distance between United States and European Union, there is a different conception of geographical indications, which, according to the prevailing American opinion, are nothing more than generic names[503] and, thus, not protectable as trademarks.[504]

It is not a casualty that one of the most influent organizations in the food and agricultural American market, namely the Consortium for Common Food Names (CCFN)[505], has as main target to impede the protection as

---

[500] On the negotiating process of geographical indications protection under CETA, see C. VIJU, *CETA and Geographical Indicators: Why a Sensitive Issue?*, CETA Policy Briefs Series, October 2013.

[501] Chapter 22, Annex I of CETA. On this point, see B. O'CONNOR, *Geographical Indications in CETA, the Comprehensive Economic and Trade Agreement between Canada and the EU*, NCTM, November 2014.

[502] Think of the letter addressed by 55 Senators of the U.S. Congress to TTIP official representative Michael Froman and to USDA Secretary Tom Vilsack on March 11th 2014, where they ask to reject any request for protecting European geographical indications within the United States.

[503] Effectively, this concept has been diffusing over time also due to the European immigrants' habit to bring with themselves to the United States certain names, certain traditions and certain products, concurring to their commercialization. On this point, see also A. MATTHEWS, *Geographical indications (GIs) in the US-EU TTIP negotiations*, CAP Reform, June 19th 2014.

[504] See also S. I. AKHTAR, V. C. JONES, *Proposed Transatlantic Trade and Investment Partnership (T-TIP): In Brief*, Congressional Research Service, June 11th 2014.

[505] CCFN is chaired by Errico Auricchio, who is part of the same family of the owner of the known Italian dairy company. Errico Auricchio is currently one of the big

geographical indications of a series of names which, conversely, the Consortium considers to be generic and, as such, a public heritage instead of a property of only some of the global producers. Actually, looking deeper, the harshness of such a dispute involves only a small part of the indications protected under the European system, namely the most renowned across the international market.

However, an essential misunderstanding remains, that is the idea that geographical indications are comparable to marks and so they may fall under the same regulation: actually, the European PDO and PGI system is certainly part of intellectual property as a subject, but it has some characteristics - as the impossibility to own the indication - which are completely different from marks. It is, as previously said, a *sui generis* system.[506]

A path to walk through for European negotiators is indeed to underline the absence of incompatibility between marks and geographical indications[507], moreover insisting on a protection model for the latters that focuses on the proper geographical part of denomination.[508]

Purists who oppose such compromises, alleging a weakening of the European protection system, may easily be answered explaining that, currently, such a protection is completely absent within the American market: TTIP negotiation is, rather, the first step to strengthen the rights of European food and agricultural producers in the United States.

This is even clearer if considering that the PDO and PGI system, however as cutting edge, has affected principally the internal market[509], while exports have not registered huge numbers.[510]

---

producers coming from Europe and established in the United States who fight to defend what they consider as generic names.

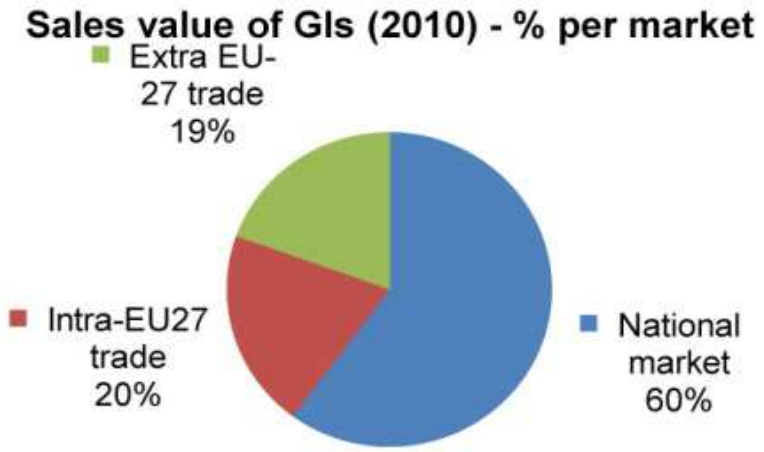
[506] See p. 104.

[507] For such a kind of proposal, see B. O'CONNOR, *Geographical Indications in TTIP The TransAtlantic Trade and Investment Partnership*, NCTM, April 2015.

[508] In this sense, for instance, the name Bresaola may be considered as generic, while the denomination Bresaola della Valtellina may be protected.

[509] See the report commissioned by DG AGRI, titled "*Value of production of agricultural products and foodstuffs, wines, aromatised wines and spirits*

Considering that the United States represents the first market in terms of value of PDO and PGI products' exports[511], it is not the case for the European Union to underestimates the importance of the chapter on geographical indications within the TTIP.[512]



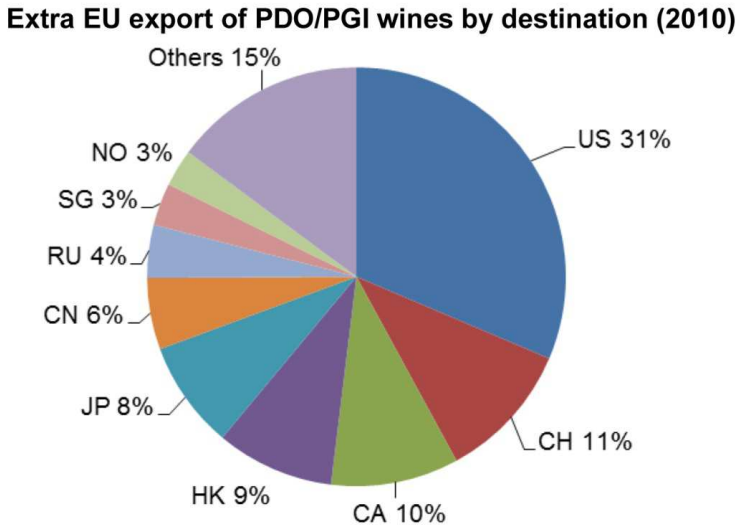
	Total exports (GI and non-GI)	GI exports	% GI/total
Wines	6 732	5 886	87%
Spirits	7 167	4 614	64%
Agri. Prod. and foodstuffs	61 713	1 007	2%
Total food and beverages	**75 612**	**11 507**	**15%**

protected by a geographical indication (GI)", of October 2012, from which are taken also the charts of this page and the one following.

[510] PDO and PGI products represent 15% of global value of exports in food, wine and agricultural sector, as highlighted in the chart. Their export accounted for some 15 million euro in 2015, according to the above mentioned *Guide to the EU's proposal on Agriculture and Geographical Indications (GIs)*.

[511] See note n. 526.

[512] The chapter on geographical indications seems to be one of the most delayed sectors among the negotiation tables of TTIP. It appears, furthermore, that many of the European consortia and producers, unsatisfied of the progress of official negotiation, have started to voluntary deal directly with their American colleagues in order to find some points of agreement.



That said, it appears as the European Union is trying to boost the discussion on geaographical discussusion: in fact, during the last negotiation round, the European officers came with a new proposal which deals with the protection for the indications of both food products and wine (and spirit) products.[513]

Generally, the Commission considers the current American system as unable to provide a satisfying protection framework for the European geographical indications, and it identifies four reasons generating such shortcomings: the level of protection for foodstuffs is sensibly lower than for wine products[514]; the trademark regime determines high costs of registration without ensuring an adequate enforcement[515]; prior marks without any genuine link with a geographical indication may have been registered; some European indications cannot be protected as trademarks due to the alleged genericity of their names.[516]

---

[513] See in depth the *European Commission Paper on Geographical Indications (GIs) in the EU – U.S. Transatlantic Trade and Investment Partnership*, the *European Commission Outline of text on Geographical Indications* and the *Draft Chapter on Trade in Wine and Spirit Drinks*.

[514] As previously pointed out: see Chapter 5.3.

[515] In fact, the mark's holder is supposed to control its mark and to prevent or challenge any abuse, given the absence of administrative controls and actions.

[516] See paragraph 1.2, *European Commission Paper on Geographical Indications (GIs) in the EU - U.S. Transatlantic Trade and Investment Partnership*.

On the grounds of the foregoing, the Commission has submitted a draft text on geographical indications which may address these problems.[517]

In the outline the European Union proposes to create a short list[518] of geographical indications similar to the CETA's one[519] and to improve the existing administrative enforcement.[520]

Nevertheless, the most important aspect of such a proposal is that the Commission keeps trying to expand the enhanced protection typical of Article 23 TRIPs to those names that currently fall under Article 22 of the same text.[521]

Instead, with regard to the wine sector negotiators of both sides are working to improve the current regulatory framework, represented by the above mentioned Wine Trade Agreement[522].

Summarily, the European Union is pushing to enhance the protection of 17 European names which American wine producers can still use in accordance with Article 6 of the agreement.

In so doing, all the provisions of the previous agreement - as amended and modified - will become an integral part of TTIP, upgrading their legal status.[523]

The European Union has so released a draft chapter on wine and spirit drinks[524] which contains all these proposals. Among the most important

---

[517] It is the *European Commission Outline of text on Geographical Indications*.

[518] See *Annex I to the EU's Paper on Geographical Indications in Transatlantic Trade and Investment Partnership*. It is intended to be an open list, so that the inital list of name could be expanded. More, it refers only to foodstuffs other than wine and spirits.

[519] See p. 127 above and Chapter 22, Annex I of CETA.

[520] See paragraph 1.3, *European Commission Paper on Geographical Indications (GIs) in the EU - U.S. Transatlantic Trade and Investment Partnership*. European Union wants particularly to impede that using the terms "kind", "like" or other next to the protected name may be considered as a lawful practice.

[521] In fact, despite redirecting to Article 22 TRIPs as for the definition of geographical indication, the *European Commission Outline of text on Geographical Indications* states at paragraph 5.2 that *"parties commit to provide to the GIs of the other party a level of protection as set as in art. 23.1 TRIPs"*.

[522] See note n. 495.

[523] In fact, the Wine Trade Agreement was approved only by the United States Administration, while TTIP will require also the approval of the Congress.

features of this text it is worth to mention the complete absence of grandfathering clauses and the establishment of a proper Committee[525] which may monitor and coordinate cooperation between parties.

[524] It is the above mentioned *Draft Chapter on Trade in Wine and Spirit Drinks.*

[525] *Ibid.*, Article 10 - Committee on trade in wines and spirit drinks.

CONCLUSIONS

In the previous pages some efforts have been spent in order to draw the most complete as possible picture of the negotiation bases of TTIP, focusing the attention on the rules governing food law within the European Union, the United States and, where it possible, also at the international level.

First of all, it has been reviewed the legal and political path which has led the parties to concretize the efforts of decades of - more or less strong - discussions in the field of international trade, ambitiously aiming to the conclusion of an agreement which covers an area corresponding to about a half of global GDP.[526]

At the same time the implications of this cooperation have been analyzed with reference to basic concepts such as sovereignty and exercise of public powers.

Specifically focusing on the issues related to food law, the work has developed around three themes of great historical and economic importance for trade between the United States and the European Union.

At first, indeed, the European and American regulations on food safety have been taken into consideration, in their diachronic and synchronic perspectives, paying particular attention to the apical bodies of the sector.

This comparison has led to enucleate some hot spots, which, however, have a high level of detail, too much to hypothesize their treatment under the horizontal chapter of TTIP on sanitary and phytosanitary measures.[527]

Secondly, the work has underlined the deep differences between the European and the American approaches towards genetically modified

---

[526] According to data provided by the World Bank for the year 2014, the United States has a GDP of almost 17,419 billion dollars, against a GDP of about 18,460 billion dollars of the European Union. World GDP is about 77,868 billion dollars.

[527] However, these issues will most likely represent the first problems to resolve after having implemented the regulatory cooperation mechanisms foreseen in the horizontal chapter of TTIP.

organisms, which is moreover a very sensitive topic for public opinion and on which a compromise, although quite impracticable in the short term, is desirable to stretch the relations between the two superpowers.[528]

Finally, wide space has been dedicated to geographical indications, considered as another topic where a strong opposition between European and American rules can be noted.

In this sense, after having analyzed the international provisions which currently regulate the subject and having performed a deep focus on wine products, the possible application perspectives of TTIP regarding the protection of such indications have been pointed out. Unlike both of the previous points, on this topic TTIP appears to be able to set a definitive regulatory framework in relations between the European Union and the United States.

Coming to conclusions, it is necessary to set out two last considerations, a microscopic one and a macroscopic one.

The first one deals with what the international policy doctrine calls Two-level game theory[529], that is a model representing the double track whereby institutional representatives act during negotiations of international agreements.

Indeed, negotiators and politicians are in the delicate position of having to take into account two different and often conflicting stakes: on one hand, they must respond to the interests of the States or organizations they

---

[528] Even in this case the role of the future regulatory cooperation comes into play.

[529] The creator of the Two-level game theory was the political scientist Robert David Putnam, who resumed and refined long debated concepts in the field of choice theory. See R. D. PUTNAM, *Diplomacy and domestic politics: the logic of two-level games*, the International Organization vol. 42, 1988, pp. 433-459. Here is a pace of the text: *"The politics of many international negotiations can usefully be conceived as a two-level game. At the national level, domestic groups pursue their interests by pressuring the government to adopt favorable policies, and politicians seek power by constructing coalitions among those groups. At the international level, national governments seek to maximize their own ability to satisfy domestic pressures, while minimizing the adverse consequences of foreign developments. Neither of the two games can be ignored by central decision-makers, solong as their countries remain interdependent, yet sovereign."*
Putnam's studies refer also to the ideas of R. E. WALTON, R. B. MCKERSIE, *A Behavioral Theory of Labor Negotiations: An Analysis of a Social Interaction System*, Cornell University Press, 1965.

represent, taking particularly care of the possible consequences of their actions on public opinion; on the other hand, they are supposed to reach a compromise with the negotiating partner, approaching and adjusting their position to the others' one.

Certainly, TTIP is not an exception to the above[530]: for instance, it is possible to look at the case of geographical indications.

The European Union, relying on a great food and culinary tradition and on a diffused awareness of such peculiarities within public opinion, is facilitated in claiming a strong protection for its geographical indications within the treaty. However, official negotiators obviously know that the other party is all but willing to accept the complete sui generis system in force in Europe and they rather have to push away the attempts to "genericization" of some brands.

On the contrary, United States are supported by the strong pressure of big national agribusiness lobbies in their efforts to prevent that a significant portion of American production may be endangered by the protection of European geographical indications. Yet similarly, when negotiating, they are full aware of the fact that the European Union will never accept an agreement that does not increase protection for its indications.

To make matter worse, it has to be considered also the macroscopic insight mentioned above, which regards the global dimension of TTIP.

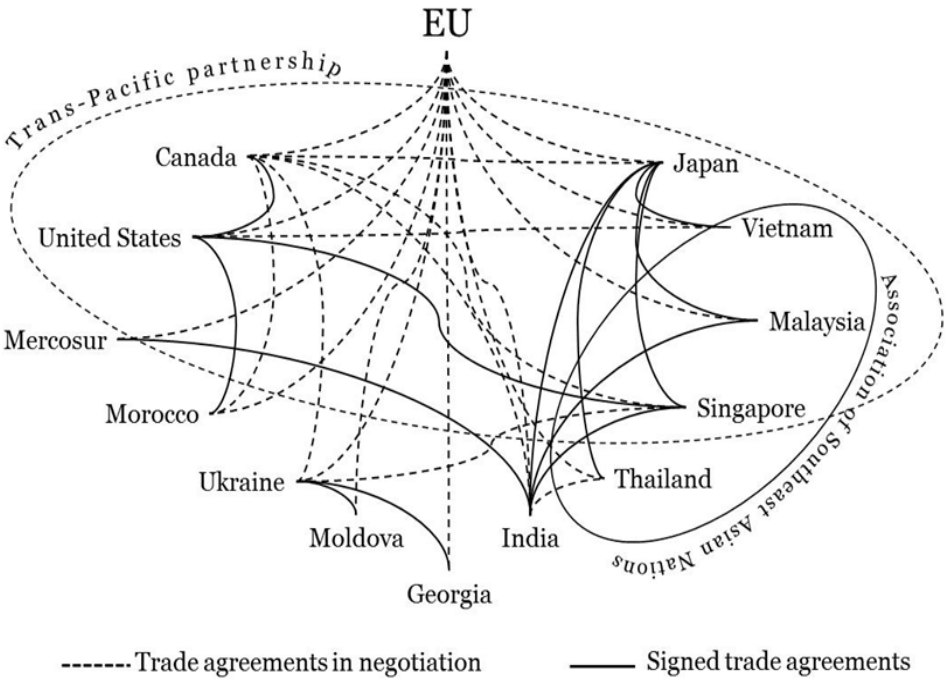
In fact, the agreement between United States and European Union cannot be considered in isolation from the wider global international trade landscape. In this sense, the reference is not only to the other multilateral treaties in which the two powers take part, but also the several concluded or currently under negotiation bilateral treaties with other States.[531]

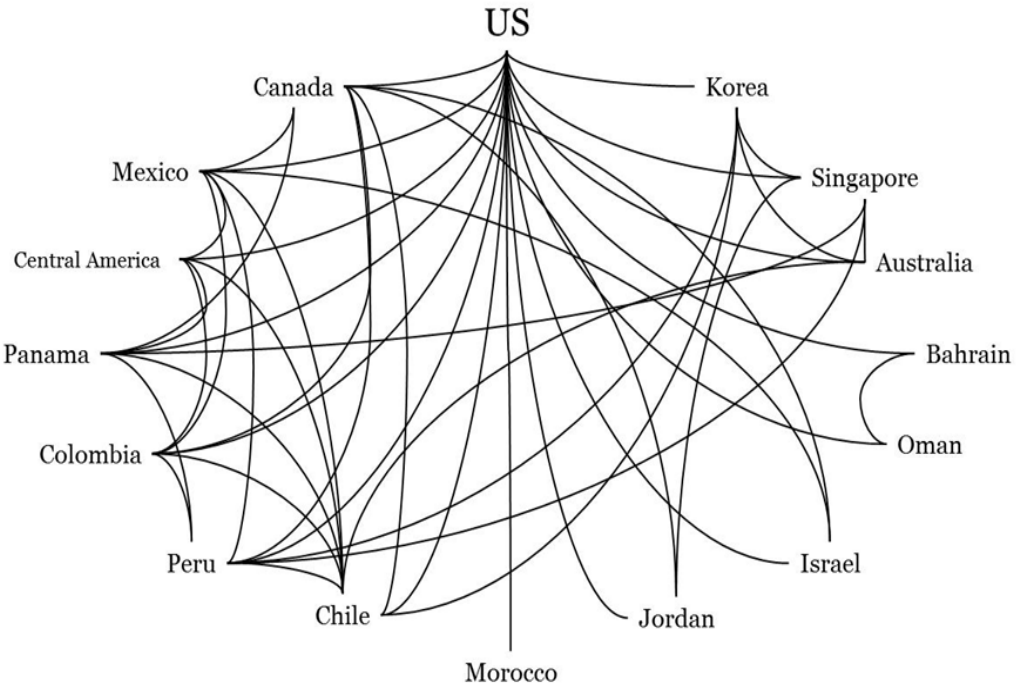
---

[530] On this point see M.A. POLLACK, G.C. SHAFFER, *supra*, pp. 80-83.

[531] In this sense, in the case of TTIP, the Two-level game theory can even be considered as outdated, and it may rather be used a Multi-level game theory. On this point see S. MEUNIER, J.F. MORIN, *No Agreement is an Island: Negotiating TTIP in a Dense Regime Complex*, in "The Politics of Transatlantic Trade Negotiations: TTIP in a Globalized World", Ashgate, 2015, pp. 173-186. The figures on the next page are taken from the latter.

The complexity of the framework results in a mutual influence of the various levels and ways in which the European Union and the United States committed themselves. The following figures may help in understanding the extent of the phenomenon.





These last considerations lead also to an important corollary for the international political level, that is the centrality of TTIP as a guide in the sector of international trade agreements.

The role of WTO on the world stage, indeed, due to the crisis of the multilateral model and the increasing favor for bilateral agreements[532], is inexorably walking on the wane[533] and TTIP can stand as a landmark, breaking the stagnation of global political and commercial situation.[534]

However, it is necessary to consider, as severally underlined above, as the positions of the European Union and the United States are quite distant on many of the issues under negotiation. Therefore, it is reasonable not to expect a great level of detail – and, thus, great revolutions - in the contents of TTIP. Nevertheless, this agreement will represent the legal basis for the future regulatory cooperation between United States and European Union, which are the two biggest world powers.

Time will tell whether it will be a role model or not.

---

[532] See E. HERFKENS, C. MICHALOPOULOS, *Multilateral, Plurilateral and Bilateral Trade: Untangling the Knots and Advancing Atlantic Commerce*, Working Paper for the 2015 Atlantic Business Forum, 2015.

[533] On this point, see diffusely R. WILKINSON, *The WTO: Crisis and the Governance of Global Trade*, Routledge, January 11th 2013 and D. C. ESTY, *The World Trade Organization's legitimacy crisis*, World Trade Review, March 2002, pp. 7-22.

[534] See F. ERIXON, *TTIP and the Structure of Global Trade Policy*, CATO Institute, October 2015. Here is an excerpt of the text: *"[...] if TTIP succeeds, the response from the larger emerging economies will hardly be to have no response."*

REFERENCES

L. ACOSTA, *Restrictions on Genetically Modified Organisms: United States*, Library of the Congress, March 2014.

S. AGARWAL, M. J. BARONE, *Emerging Issues for Geographical Indication Branding Strategies*, MATRIC Research Papers, January 2005.

S. I. AKHTAR, V. C. JONES, *Proposed Transatlantic Trade and Investment Partnership (T-TIP): In Brief*, Congressional Research Service, June 11th 2014.

F. ALBISINNI, *Dalla legislazione al diritto alimentare: tre casi*, in *"Rivista di diritto alimentare"*, 2007, n. 1.

A. ALEMANNO, *The Shaping of the Precautionary Principle by European Courts: from Scientific Uncertainty to Legal Certainty*, in "*Valori costituzionali e nuove politiche del diritto"*, Halley, 2007.

A. ALEMANNO, *The Transatlantic Trade and Investment Partnership and the Parliamentary dimension of Regulatory Cooperation*, Directorate-General for External Policies of the Union, April 2014.

A. ALEMANNO, *The Regulatory Cooperation Chapter of the Transatlantic Trade and Investment Partnership: Institutional Structures and Democratic Consequences*, Journal of International Economic Law, August 28th 2015.

A. ALEMANNO, S. GABBI, *Foundations of EU Food Law and Policy. Ten years of the European Food Safety Authority*, Ashgate, 2014.

E. M. APPIANO, S. DINDO, *Le pratiche enologiche e la tutela delle denominazioni d`origine nell`Accordo UE/USA sul commercio del vino*, in "*Contratti e Impresa - Europa"* vol. 1, 2007.

F. D. ASPLIN, R. B. A. CARNAGHAN, *The toxicity of certain groundnut meals for poultry with special reference to their effect on ducklings and chickens*, in *"Veterinary Record vol.73"*, 1961.

T. ATKINS, R. JOHNSON, *Appellation as an indicator of quality*, International Journal of Wine Business Research, vol. 22, 2007.

E. BARHAM, J. BINGEN, C. C. HINRICHS, *Geographical Indications in the USA*, in *"Labels of origin for food: local development, global recognition"*, CAB International, May 27th 2011.

R. BENDINI, *Factsheet on the European Union - The European Union and the World Trade Organization*, May 2015.

L. BERESFORD, *Geographical Indications: The Current Landscape*, in *"Fordham Intellectual Property, Media and Entertainment Law Journal"*, vol. 17, 2007.

N. BERNASCONI-OSTERWALDER, *Environment and Trade. A Guide to WTO Jurisprudence*, Earthscan, 2006.

B. BONARDI, *TTIP: un'occasione da non perdere. Intervista esclusiva a Paola Testori Coggi*, ne "*Il fatto alimentare*", August 7th 2015.

P. BORGHI, *L'agricoltura nel trattato di Marrakech. Prodotti agricoli e alimentari nel diritto del commercio internazionale*, Giuffrè, 2004.

R. M. BRATSPIES, *Some thoughts on the American approach to regulating genetically modified organisms*, Kansas Journal of Law & Pubic Policy vol. 16, 2007.

R. M. BRATSPIES, *Is anyone regulating? The curious state of GMO governance in the United States*, Vermont Law Review vol. 37, 2013.

D. BRESSANINI, *Il Made in Italy contaminato dagli OGM*, in *"Scienza in cucina"*, July 15th 2013.

D. BRESSANINI, *Mais OGM: un bigino per i neoministri*, in "*Scienza in cucina"*, April 25th 2014.

D. BRESSANINI, B. MAUTINO, *Contro natura. Dagli OGM al "bio", falsi allarmi e verità nascoste del cibo che portiamo in tavola*, Rizzoli, May 2015.

M. CANAVARI, N. CANTORE, A. CASTELLINI, E. PIGNATTI, R. SPADONI, *International marketing and trade of quality food products*, Wageningen Academic Publishers, 2009.

F. CATANZARO, F. LICCIARDO, *La riforma del Regolamento (CEE) 2081/92 sulla protezione delle indicazioni geografiche e delle denominazioni di origine*, in "*Agriregionieuropa*", June 2006.

L. COLOMBO, *Grano o grane. La sfida OGM in Italia*, Manni Editori, 2006.

P. A. CURTIS, *Guide to food laws and regulations*, Blackwell Publishing, 2005.

C. M. DAVIS, *"Fast-track" or expedited procedures: their purpose, elements, and implications*, Congressional Research Service, July 2003.

M. DESQUILBET, S. MONIER-DILHAN, *Are geographical indications a worthy quality label? A framework with endogenous quality choice*, Toulouse School of Economics Working Paper Series, December 2011.

M. DI SISTO, *Contro il TTIP, con i piedi per terra. Sovranità, agricoltura, OGM, cibo: tutto quello che vorreste sapere sul negoziato USA e UE e vi stanno raccontando solo in parte*, Fairwatch, February 23rd 2014.

F. DI TODARO, *La globalizzazione? Mangiamo tutti le stesse cose*, in *"La Stampa"*, July 21st 2014.

E. DOHLMAN, *Mycotoxin Hazards and Regulations. Impacts on food and animal feed crop trade*, in *"International Trade and Food Safety: Economic Theory and Case Studies"*, Economic Research Service of USDA, November 2003.

J. DUNOFF, in *Globalization and the environment: the limits of the law*, in *"Security, Trade and Environmental Policy: a US/European Union Transatlantic Agenda"*, Kluwer Academic Publishers, 2000.

G. DUTFIELD, *Geographical Indications and Agricultural Community development: is the European Model Appropriate for Developing Countries?*, in *"The Intellectual Property and Food Project From Rewarding Innovation and Creation to Feeding the World"*, Ashgate, January 2014.

B. EBERLEIN, E. GRANDE, *Beyond delegation: transnational regulatory regimes and the EU regulatory state*, in *"Journal of European Public Policy"*, Routledge, 2005.

M. A. ECHOLS, *Geographical Indications for Food Products: International Legal and Regulatory Perspectives*, Kluwer Law International, 2008.

F. ERIXON, *TTIP and the Structure of Global Trade Policy*, CATO Institute, October 2015.

D. C. ESTY, *The World Trade Organization's legitimacy crisis*, World Trade Review, March 2002.

G. E. EVANS, M. BLAKENEY, *The Protection of Geographical Indications After Doha: Quo Vadis?*, Journal Of International Economic Law, September 2006.

H. W. FARNAM, C. DAY, *Chapters in the History of Social Legislation in the United States to 1860*, The Lawbook Exchange, 1938.

G. FEKETEKUTY, *The next generation of world trade policy development*, in *"Security, Trade and Environmental Policy: a US/European Union Transatlantic Agenda"*, Kluwer Academic Publishers, 2000.

I. F. FERGUSSON, *Trade Promotion Authority (TPA) and the Role of Congress in Trade Policy*, Congressional Research Service, June 15th 2015.

M. FERRARI, *La dimensione proprietaria delle indicazioni geografiche. Uno studio di diritto comparato*, Editoriale Scientifica, 2015.

M. FERRARI, U. IZZO, *Diritto alimentare comparato. Regole del cibo e ruolo della tecnologia*, il Mulino, 2012.

N. D. FORTIN, *Food Regulation. Law, Science, Policy and Practice*, Wiley, 2009.

D. GAETA, P. CORSINOVI, *Traditional Terms and Appellation wines: debates insight of TTIP negotiation*, 145th EAAE Seminar, April 2015.

D. GANGJEE, *Relocating the Law of Geographical Indications*, Cambridge University Press, 2012.

D. J. GERVAIS, *Reinventing Lisbon: The Case for a Protocol to the Lisbon Agreement (Geographical Indications)*, Chicago Journal of International Law, June 2010.

D. GIOVANNUCCI, T. JOSLING, W. KERR, B. O'CONNOR, M. T. YEUNG, *Guide to Geographical Indications linking products and their origins*, International Trade Center, 2009.

G. GOETZ, *Who Inspects What? A Food Safety Scramble*, in *"Food safety news"*, December 16th 2010.

S. D. GOLDBERG, *Who Will Raise the White Flag? The Battle between the United States and the European Union over the Protection of Geographical Indications,* Journal of International Law, 2001.

A. GOYAL, *The WTO and International Environmental Law. Towards Conciliation*, Oxford University Press, 2006.

K. G. GRUNERT, *Food quality and safety: consumer perception and demand*, European Review of Agricultural Economics vol. 32, 2005.

C. E. HANRAHAN, *The European Union's Ban on Hormone-Treated Meat*, Congressional Research Service, December 19th 2000.

C. E. HANRAHAN, *Geographical Indications and WTO Negotiations*, Congressional Research Service, July 14th 2003.

K. HARDEE, *Insuring the Safety of Foreign Foods*, in *"Food Safety Magazine"*, February 23rd 2016.

E. HERFKENS, C. MICHALOPOULOS, *Multilateral, Plurilateral and Bilateral Trade: Untangling the Knots and Advancing Atlantic Commerce*, Working Paper for the 2015 Atlantic Business Forum, 2015.

J. HILARY, *Il Partenariato Transatlantico per il Commercio e gli Investimenti. Una carta per la deregolamentazione, un attacco ai posti di lavoro, la fine della democrazia*, Rosa-Luxemburg-Stiftung, Bruxelles, March 2014.

C. HILLION, P. KOUTRAKOS, *Mixed agreements revisited: The EU and its Member States in the world*, Bloomsbury Publishing, 2010.

P. J. HILTS, *Protecting America's Health: The Fda, Business, and One Hundred Years of Regulation*, Alfred. A. Knopf, 2003.

S. HOREL, *A toxic affair. How the chemical lobby blocked action on hormone disrupting chemicals*, Corporate Europe Observatory, May 2015.

J. F. HORNBECK, *Trade promotion authority (TPA): issues, options, and prospects for renewal*, Congressional Research Service, July 2008.

G. W. HUDLER, *Magical Mushrooms, Mischievous Molds,* Princeton University Press, 2000.

R. HUNTER, *Why TTIP is stuck in the muck*, in *"Politico"*, January 16th 2016.

T. INMAN, *Foundation for a new theory and practice of medicine*, John Churchill, 1860.

R. JOHNSON, *The U.S.-EU Beef Hormone Dispute*, Congressional Research Service, January 14th 2015.

R. JOHNSON, *U.S.-EU Poultry Dispute on the use of Pathogen Reduction Treatments (PRTs)*, Congressional Research Service, January 14th 2015.

R. JOHNSON, *The Federal Food Safety System: A Primer*, Congressional research service, January 17th 2014.

R. JOHNSON, J. BRUWER, *Regional brand image and perceived wine quality: the consumer perspective*, International Journal of Wine Business Research, vol. 19, 2007.

T. E. JOSLING, D. ROBERTS, A. HASSAN, *The Beef-Hormone Dispute and its implications for Trade Policy*, September 1999.

W. A. KERR, J. E. HOBBS, *Consumers, Cows and Carousels: Why the Dispute over Beef Hormones is Far More Important than its Commercial Value*, in *The WTO and the Regulation of International Trade*, Edward Elgar Publishing, 2005.

C. K. KHOURY, *Increasing homogeneity in global food supplies and the implications for food security*, Proceedings of the National Academy of Sciences, March 3rd 2014.

P. KOUTRAKOS, *EU International Relations Law*, Bloomsbury Publishing, 2006.

L. KRÄMER, *The Roots of Divergence: a European Perspective*, in *"Green Giants? Environmental Policies of the United States and the European Union"*, MIT Press, 2004.

R. D. LAMB, *American chamber of horrors: the truth about food and drugs*, Farrar & Rinehart, 1936.

J. T. LAPSLEY, *Bottled Poetry: Napa Winemaking from Prohibition to the Modern Era*, University of California Press, 1996.

J. LAU, *Same Science, Different Policies: Regulating Genetically Modified Foods in the U.S. and Europe*, in *"Science in the news"*, August 9th 2015.

R. LAWLEY, *Aflatoxins*, in *"Food Safety Watch"*, February 1st 2013.

D. LYNCH, D. VOGEL, *The Regulation of GMOs in Europe and the United States: A Case-Study of Contemporary European Regulatory Politics*, Council of Foreign Relations Press, April 5th 2001.

C. MACMAOLÁIN, *Food Law: European, Domestic and International Frameworks*, Bloomsbury Publishing, April 30th 2015.

A. MATTHEWS, *Geographical indications (GIs) in the US-EU TTIP negotiations*, CAP Reform, June 19th 2014.

J. A. MCMAHON, M. G. DESTA, *Research Handbook on the WTO Agriculture Agreement*, Edward Elgar, 2012.

E. K. MELTZER, *"Pass the Parmesan? What you need to know about Geographical Indications and Trademarks"*, in *"Virginia Lawyer"*, June 2002.

L. MENAPACE, G. COLSON, C. GREBITUS, M. FACENDOLA, *Consumer preferences for country-of-origin, geographical indication,*

and protected designation of origin labels, Iowa State University, November 2009.

R. MENDELSON, *From demon to darling: a legal history of wine in America*, University of California Press, 2009.

C. MIELING, *Are you really going to eat that? Product tracing, the Food Safety Modernization Act, and the promise of RFID*, Illinois Journal of Law, Technology, and Policy, May 2014.

S. MEUNIER, J. F. MORIN, *No Agreement is an Island: Negotiating TTIP in a Dense Regime Complex*, in *"The Politics of Transatlantic Trade Negotiations: Ttip in a Globalized World"*, Ashgate, 2015.

J. F. MORIN, *Multilateralising TRIPS-Plus Agreements: Is the US Strategy a Failure?*, Journal of World Intellectual Property, 2009.

K. M. MURPHY, *Conflict, confusion, and bias under TRIPs Articles 22-24*, American University International Law Review, 2004.

A. NELSEN, *EU dropped pesticide laws due to US pressure over TTIP, documents reveal*, in *"The Guardian"*, Brussels, May 22nd 2015.

N. NOTARO, *Judicial approaches to trade and environment: the EC and the WTO*, Cameron May, 2003.

B. O'CONNOR, *The Law of Geographical Indications*, Cameron May, 2004.

B. O'CONNOR, *Indicazioni Geografiche: alcune riflessioni sulla prassi dell'Ufficio Marchio e Brevetti degli Stati Uniti e l'accordo TRIPs*, in *"Rivista di diritto alimentare"*, October 2013.

B. O'CONNOR, *Geographical Indications in CETA, the Comprehensive Economic and Trade Agreement between Canada and the EU*, NCTM, November 2014.

B. O'CONNOR, *Geographical Indications in TTIP The TransAtlantic Trade and Investment Partnership*, NCTM, April 2015.

D. PALMER, *US trade vote puts TTIP on faster track*, in *"Politico"*, June 30th 2015.

R. PALMER, GMO *Health Risks: What The Scientific Evidence Says*, in *"International Business Times"*, March 30th 2013.

F. R. PARKER, *FDA Administrative Enforcement Manual*, Taylor and Francis, 2005.

S. PENDORF, *Regulating the environmental release of genetically engineered-organisms: Foundation on Economic Trends v. Heckler*, Florida State University Law Review, 1985.

M. J. PETERSON, *The EU-US Dispute over Regulation of Genetically Modified Organisms, Plants, Feeds, and Foods - Case Summary*, International Dimensions of Ethics Education in Science and Engineering, 2010.

D. PILLING, *It won't be easy to build an 'anyone but China' club*, in *"Financial Times"*, May 22nd 2013.

E. PIZZULLI, *Foundation on Economic Trends v. Heckler: Genetic Engineering and NEPA's EIS Requirement*, Pace Environmental Law Review vol. 2, 1984.

M. A. POLLACK, *The Political Economy of the Transatlantic Partnership*, Robert Schuman Centre for Advanced Studies, June 2003.

M. A. POLLACK, G. C. SHAFFER, *When Cooperation Fails: The International Law and Politics of Genetically Modified Foods*, Oxford University Press, May 21st 2009.

R. D. PUTNAM, *Diplomacy and domestic politics: the logic of two-level games*, International Organization vol. 42, 1988.

F. RAMPINI, *TTIP, la posta in gioco*, in *"Estremo Occidente"*, April 20th 2015.

P. K. RAO, *Environmental Trade Disputes and the WTO*, Pinninti Publishers, 2001.

W. P. ROENIGK, *Transatlantic Trade and Investment Partnership: Achieving the Potential*, October 30th 2013.

B. ROSE, *No More Whining About Geographical Indications: Assessing the 2005 Agreement Between the United States and the European Community on the Trade in Wine*, Houston Journal of International Law, 2007.

V. RUBINO, *La protezione delle denominazioni geografiche dei prodotti alimentari nell'Unione europea dopo il regolamento 1151/2012*, in *"Rivista di diritto alimentare"*, 2013.

H. G. RUSE-KHAN, *The International Law Relation between TRIPS and Subsequent TRIPS-Plus Free Trade Agreements: Towards Safeguarding TRIPS Flexibilities?*, Journal of Intellectual Property Law, May 19th 2011.

C. SAGAN, *Demon-haunted world: science as a candle in the dark*, Random House, 1995.

G. E. SÉRALINI, *Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize*, Food and Chemical Toxicology, November 2012.

U. SINCLAIR, *The Jungle*, Doubleday, February 26th 1906.

F. SINDICO, *The GMO Dispute before the WTO: Legal Implications for the Trade and Environment Debate*, Fondazione Eni Enrico Mattei, January 2005.

J. M. SMITH, *Why certain Trade Agreements are approved as Congressional-Executive Agreements rather than Treaties*, Congressional Research Service, April 15th 2013.

L. SOFRI, *Notizie che non lo erano. Perché certe storie sono troppo belle per essere vere*, Rizzoli, 2015.

M. SOLIS, *The Containment Fallacy: China and the TPP*, Brookings Institutions, May 24th 2013.

C. R. SUNSTEIN, *Il diritto della paura. Oltre il principio di precauzione*, il Mulino, 2010.

C. I. P. THOMAS, *In food we trust. The politics of purity in American food regulation*, University of Nebraska Press, 2014.

J. A. THOMSON, *Seeds for the Future: The Impact of Genetically Modified Crops on the Environment*, Comstock Publishing Associates, 2007.

L. UNNEVEHR, D. GRACE, *Aflatoxins: Finding solutions for improved food safety*, International Food Policy Research Institute, September 30th 2013.

B. VAN DER MUELEN, *EU Food Law Handbook*, Wageningen Publishers, 2014.

C. VIJU, *CETA and Geographical Indicators: Why a Sensitive Issue?*, CETA Policy Briefs Series, October 2013.

H. VON DER BURCHARD, *Last chance for transatlantic trade pact*, in *"Politico"*, April 11th 2016.

R. E. WALTON, R. B. MCKERSIE, *A Behavioral Theory of Labor Negotiations: An Analysis of a Social Interaction System*, Cornell University Press, 1965.

J. WEISMAN, *Trade Authority Bill wins final approval in Senate*, in *"New York Times"*, June 24th 2015.

R. WILKINSON, *The WTO: Crisis and the Governance of Global Trade*, Routledge, January 11th 2013.

D. WIRTH, *The Transatlantic GMO Dispute Against the European Communities. Some Preliminary Thoughts*, in *"EU and WTO Law: How Tight is the Legal Straitjacket for Environmental Product Regulation?"*, Brussels University Press, 2006.

D. WIRTH, *The World Trade Organization Dispute Concerning Genetically Modified Organisms: Precaution Meets International Trade Law*, Vermont Law Review vol. 37, 2013.

The Student Paper Series of the Trento Lawtech Research Group is published since Fall 2010

http://www.lawtech.jus.unitn.it/index.php/student-paper-series?start=1

Freely downloadable papers already published:

STUDENT PAPER N. 27

Privacy and Health Data: a Comparative Analysis

FOGLIA CAROLINA (2016) Privacy and Health Data: a Comparative Analysis. The Trento Law and Technology Research Group. Student Paper Series; 27. Trento: Università degli Studi di Trento.
ISBN 978-88-8443-546-0

STUDENT PAPER N. 26

Big Data: Privacy and Intellectual Property in a Comparative Perspective

SARTORE FEDERICO (2016) Big Data: Privacy and Intellectual Property in a Comparative Perspective. The Trento Law and Technology Research Group. Student Paper Series; 26. Trento: Università degli Studi di Trento.
ISBN 978-88-8443-534-7

STUDENT PAPER N. 25

Leggere (nel)la giurisprudenza: 53 sentenze inedite in tema di responsabilità civile nelle analisi di 53 annotatori in formazione = Reading (in) the caselaw: 53 unpublished judgements dealing with civil liability law analyzed with annotations and comments by 53 students during their civil law course

REMO ANDREOLLI, DALILA MACCIONI, ALBERTO MANTOVANI, CHIARA MARCHETTO, MARIASOLE MASCHIO, GIULIA MASSIMO, ALICE MATTEOTTI, MICHELE MAZZETTI, PIERA MIGNEMI, CHIARA MILANESE, GIACOMO MINGARDO, ANNA LAURA MOGETTA, AMEDEO MONTI, SARA MORANDI, BENEDETTA MUNARI, EDOARDO NADALINI, SERENA NANNI,

VANIA ODORIZZI, ANTONIA PALOMBELLA, EMANUELE PASTORINO, JULIA PAU, TOMMASO PEDRAZZANI, PATRIZIA PEDRETTI, VERA PERRICONE, BEATRICE PEVARELLO, LARA PIASERE, MARTA PILOTTO, MARCO POLI, ANNA POLITO, CARLO ALBERTO PULEJO, SILVIA RICCAMBONI, ROBERTA RICCHIUTI, LORENZO RICCO, ELEONORA RIGHI, FRANCESCA RIGO, CHIARA ROMANO, ANTONIO ROSSI, ELEONORA ROTOLA, ALESSANDRO RUFFINI, DENISE SACCO, GIULIA SAKEZI, CHIARA SALATI, MATTEO SANTOMAURO, SILVIA SARTORI, ANGELA SETTE, BIANCA STELZER, GIORGIA TRENTINI, SILVIA TROVATO, GIULIA URBANIS, MARIA CRISTINA URBANO, NICOL VECCARO, VERONICA VILLOTTI, GIULIA VISENTINI, LETIZIA ZAVATTI, ELENA ZUCCHI (2016) Leggere (nel)la giurisprudenza: 53 sentenze inedite in tema di responsabilità civile nelle analisi di 53 annotatori in formazione = Reading (in) the caselaw: 53 unpublished judgements dealing with civil liability law analyzed with annotations and comments by 53 students during their civil law course. The Trento Law and Technology Research Group. Student Paper Series; 25. Trento: Università degli Studi di Trento. ISBN 978-88-8443-664-1

STUDENT PAPER N. 24

La digitalizzazione del prodotto difettoso: stampa 3D e responsabilità civile= The Digital Defective Product: 3D Product and Civil Liability

CAERAN, MIRCO (2016) La digitalizzazione del prodotto difettoso: stampa 3D e responsabilità civile= The Digital Defective Product: 3D Product and Civil Liability. The Trento Law and Technology Research Group. Student Papers Series; 24. Trento: Università degli Studi di Trento. ISBN 978-88-8443-663-4

STUDENT PAPER N. 23

La gestione della proprietà intellettuale nelle università australiane = Intellectual Property Management in Australian Universities

CHIARUTTINI, MARIA OTTAVIA (2015) La gestione della proprietà intellettuale nelle università australiane = Intellectual Property Management in Australian Universities. The Trento Law and Technology Research Group. Student Papers Series; 23. Trento: Università degli Studi di Trento. ISBN 978-88-8443-626-9

STUDENT PAPER N. 22

Trasferimento tecnologico e realtà locale: vecchie problematiche e nuove prospettive per una collaborazione tra università, industria e territorio = Technology Transfer and Regional Context: Old Problems and New Perspectives for a Sustainable Co-operation among University, Enterpreunership and Local Economy

CALGARO, GIOVANNI (2014) Trasferimento tecnologico e realtà locale: vecchie problematiche e nuove prospettive per una collaborazione tra università, industria e territorio. The Trento Law and Technology Research Group. Student Papers Series; 22. Trento: Università degli Studi di Trento. ISBN 978-88-8443-525-5

STUDENT PAPER N. 21

La responsabilità dell'Internet Service Provider per violazione del diritto d'autore: un'analisi comparata = Internet Service Provider liability and copyright infringment: a comparative analysis.

IMPERADORI, ROSSELLA (2014) La responsabilità dell'Internet Service Provider per violazione del diritto d'autore: un'analisi comparata. The Trento Law and Technology Research Group. Student Papers Series; 21. Trento: Università degli Studi di Trento. ISBN 978-88-8443-572-9

STUDENT PAPER N. 20

Open innovation e patent: un'analisi comparata = Open innovation and patent: a comparative analysis

PONTI, STEFANIA (2014) Open innovation e patent: un'analisi comparata. The Trento Law and Technology Research Group. Student Papers Series; 20. Trento: Università degli Studi di Trento. ISBN 978-88-8443-573-6

STUDENT PAPER N. 19

La responsabilità civile nell'attività sciistica = Ski Accidents and Civil Liability

CAPPA, MARISA (2014) La responsabilità civile nell'attività sciistica = Ski Accidents and Civil Liability. The Trento Law and Technology Research

Group. Student Papers Series; 19. Trento: Università degli Studi di Trento. ISBN 978-88-8443-548-4

STUDENT PAPER N. 18

Biodiversità agricola e tutela degli agricoltori dall'Hold-Up brevettuale: il caso degli OGM = Agricultural Biodiversity and the Protection of Farmers from Patent Hold-Up: The Case of GMOs

TEBANO, GIANLUIGI (2014) Biodiversità agricola e tutela degli agricoltori dall'Hold-Up brevettuale: il caso degli OGM. The Trento Law and Technology Research Group. Student Papers Series; 18. Trento: Università degli Studi di Trento. ISBN 978-88-8443-527-9

STUDENT PAPER N. 17

Produrre e nutrirsi "bio": analisi comparata del diritto degli alimenti biologici = Producing and Eating "Bio": A Comparative Analisys of the Law of Organic Food

MAFFEI, STEPHANIE (2013) Produrre e nutrirsi "bio" : analisi comparata del diritto degli alimenti biologici. The Trento Law and Technology Research Group. Student Paper Series; 17. Trento: Università degli Studi di Trento. ISBN 978-88-8443-516-3

STUDENT PAPER N. 16

La tutela delle indicazioni geografiche nel settore vitivinicolo: un'analisi comparata = The Protection of Geographical Indications in the Wine Sector: A Comparative Analisys

SIMONI, CHIARA (2013) La tutela delle indicazioni geografiche nel settore vitivinicolo: un'analisi comparata. The Trento Law and Technology Research Group. Student Papers Series; 16. Trento: Università degli Studi di Trento.

STUDENT PAPER N. 15

Regole di sicurezza e responsabilità civile nelle attività di mountain biking e downhill montano

SALVADORI, IVAN (2013) Regole di sicurezza e responsabilità civile nelle attività di mountain biking e downhill montano. Trento Law and Technology Research Group. Student Paper; 15. Trento: Università degli Studi di Trento.

STUDENT PAPER N. 14

Plagio, proprietà intellettuale e musica: un'analisi interdisciplinare

VIZZIELLO, VIVIANA (2013) Plagio, proprietà intellettuale e musica: un'analisi interdisciplinare. Trento Law and Technology Research Group. Student Paper; 14. Trento: Università degli Studi di Trento.

STUDENT PAPER N.13

The Intellectual Property and Open Source Approaches to Biological Material

CARVALHO, ALEXANDRA (2013) The Intellectual Property and Open Source Approaches to Biological Material. Trento Law and Technology Research Group. Student Paper Series; 13. Trento: Università degli Studi di Trento.

STUDENT PAPER N.12
Per un'archeologia del diritto alimentare: 54 anni di repertori giurisprudenziali sulla sicurezza e qualità del cibo (1876-1930)

TRESTINI, SILVIA (2012) Per un'archeologia del diritto alimentare: 54 anni di repertori giurisprudenziali sulla sicurezza e qualità del cibo (1876-1930) = For an Archeology of Food Law: 54 Years of Case Law Collections Concerning the Safety and Quality of Food (1876-1930). The Trento Law and Technology Research Group. Student Papers Series, 12.

STUDENT PAPER N.11
Dalle Alpi ai Pirenei: analisi comparata della responsabilità civile per attività turistico-ricreative legate alla montagna nel diritto italiano e spagnolo

PICCIN, CHIARA (2012) Dalle Alpi ai Pirenei: analisi comparata della responsabilità civile per attività turistico-ricreative legate alla montagna nel diritto italiano e spagnolo = From the Alps to the Pyrenees: Comparative

Analysis of Civil Liability for Mountain Sport Activities in Italian and Spanish Law. The Trento Law and Technology Research Group. Student Papers Series, 11

STUDENT PAPER N.10
Copynorms: Norme Sociali e Diritto d'Autore

PERRI, THOMAS (2012) Copynorms: Norme Sociali e Diritto d'Autore = Copynorms: Social Norms and Copyright. Trento Law and Technology Research Group. Students Paper Series, 10

STUDENT PAPER N. 9

L'export vitivinicolo negli Stati Uniti: regole di settore e prassi contrattuali con particolare riferimento al caso del Prosecco

ALESSANDRA ZUCCATO (2012), L'export vitivinicolo negli Stati Uniti: regole di settore e prassi contrattuali con particolare riferimento al caso del Prosecco **=** Exporting Wines to the United States: Rules and Contractual Practices with Specific Reference to the Case of ProseccoTrento: Università degli Studi di Trento (Trento
Law and Technology Research Group. Students Paper Series 9)

STUDENT PAPER N.8

Equo compenso e diritto d'autore: un'analisi comparata = Fair Compensation and Author's Rights: a Comparative Analysis.

RUGGERO, BROGI (2011) Equo compenso e diritto d'autore: un'analisi comparata = Fair Compensation and Author's Rights: a Comparative Analysis. Trento: Università degli Studi di Trento (TrentoLawand Technology Research Group. Student Papers Series, 8)

STUDENT PAPER N.7
Evoluzione tecnologica e mutamento del concetto di plagio nella musica

TREVISA, ANDREA (2012) Evoluzione tecnologica e mutamento del concetto di plagio nella musica = Technological evolution and change of the notion of plagiarism in music Trento: Università degli Studi di Trento (Trento Law and Technology Research Group. Students Paper Series 7)

STUDENT PAPER N.6

Il trasferimento tecnologico università-imprese: profili giuridici ed economici

SIRAGNA, SARA (2011) Il trasferimento tecnologico università-imprese: profili giuridici ed economici = University-Enterprises Technological Transfer: Legal and Economic issues Trento: Università degli Studi di Trento (Trento Law and Technology Research Group. Students Paper Series 6)

STUDENT PAPER N.5
Conciliare la responsabilità medica: il modello "generalista" italiano a confronto col modello "specializzato" francese

GUERRINI, SUSANNA (2011) Conciliare la responsabilità medica: il modello "generalista" italiano a confronto col modello "specializzato" francese = Mediation & Medical Liability: The Italian "General Approach" Compared to the Specialized Model Applied in FranceTrento: Università degli Studi di Trento (Trento Law and Technology Research Group. Students Paper Series 5)

STUDENT PAPER N.4
"Gun Control" e Responsabilità Civile: una comparazione fra Stati Uniti e Italia

PODETTI, MASSIMILIANO (2011) "Gun Control" e Responsabilità Civile: una comparazione fra Stati Uniti e Italia = Gun Control and Tort Liability: A Comparison between the U.S. and Italy Trento: Università degli Studi di Trento. (Trento Law and Technology Research Group. Students Paper Series 4)

STUDENT PAPER N.3
Smart Foods e Integratori Alimentari: Profili di Regolamentazione e Responsabilità in una comparazione tra Europa e Stati Uniti

TOGNI, ENRICO (2011) Smart Foods e Integratori Alimentari: Profili di Regolamentazione e Responsabilità in una comparazione tra Europa e Stati Uniti = Smart Foods and Dietary Supplements: Regulatory and Civil Liability Issues in a Comparison between Europe and United States Trento: Università degli Studi di Trento - (Trento Law and Technology Research Group. Students Paper Series; 3)

STUDENT PAPER N.2

Il ruolo della responsabilità civile nella famiglia: una comparazione tra Italia e Francia

SARTOR, MARTA (2010) Il ruolo della responsabilità civile nella famiglia: una comparazione tra Italia e Francia = The Role of Tort Law within the Family: A Comparison between Italy and France Trento: Università degli Studi di Trento - (Trento Law and Technology Research Group. Students Paper Series; 2)

STUDENT PAPER N.1
Tecnologie belliche e danno al proprio combattente: il ruolo della responsabilità civile in una comparazione fra il caso statunitense dell'Agent Orange e il caso italiano dell'uranio impoverito

RIZZETTO, FEDERICO (2010) Tecnologie belliche e danno al proprio combattente: il ruolo della responsabilità civile in una comparazione fra il caso statunitense dell'Agent Orange e il caso italiano dell'uranio impoverito = War Technologies and Home Soldiers Injuries: The Role of Tort Law in a Comparison between the American "Agent Orange" and the Italian "Depleted Uranium" Litigations Trento: Università degli Studi di Trento - (Trento Law and Technology Research Group. Students Paper Series; 1)