GMOs Across the Atlantic

Sacrificing Precaution in the Name of Free Trade?

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1. Introduction

Kofi Annan once said "[...] that arguing against globalisation is like arguing against the laws of gravity".[1] The world has evolved into a place of omnipresent interconnectivity where people are linked across borders by economic, political, friendly and family ties. Although risks have likewise become globalised in the process, risk management still largely constitutes a national issue. While transnational food scandals as the BSE crisis in 1997 or the horse meat scandal of 2013 have shaken consumers within and beyond the European Union (EU), Member States (MS) nonetheless continue to insist on their sovereignty to approach and handle uncertain risks by themselves. There are a variety of levels related to dealing with uncertain risks that are affected by this controversy. Amongst them are science as in risk assessment, law as in risk regulation and politics as in risk management and the overall coordinating risk governance processes. As neither science or law nor politics are able to provide fully sound and satisfying solutions for coping with uncertain risks, controversy and heated debate remains even long after a political decision has been made on a case. It is striking how all these disciplines attempt to appropriately respond to uncertainty, while they do actually add more complexity and differing opinions. There consequently is no solid ground for policy-makers to base their final decisions on and justify the particular regulation or acceptance of risks.

It remains an issue how politics can effectively work in light of uncertainty. This is especially important when considering the effects of globalisation. Through international trade and the flow of goods through the world economy, products associated with uncertain risk cross national borders on a daily basis and need to be regulated.[2] The ongoing negotiations on a free trade agreement between the European Union and the United States of America have highlighted the difficulties regarding this process. If successfully concluded, supposedly by the end of 2014, the Transatlantic Trade and Investment Partnership (TTIP) would constitute the largest free trade zone worldwide and both the EU and the US would benefit tremendously.[3] However, negotiations have not gone so smoothly due to prevailing disagreement over the rules that should apply for the TTIP.[4] With regards to food safety, the EU and the US have already had difficulties in the past to agree on a common denominator. Related differences and incompatibilities

1 Crossette 03-09-2000.

2 Linnerooth-Bayer *et al*. 2001.

3 Felbermayr, Heid & Lehwald 2013.

4 Sandler, Travis & Rosenberg Trade Report 09-04-2014.

become evident in the debate on food safety.[5] Although consumer protection is a highly-ranked principle for both parties, there is little agreement on what requires strict protective measures and what should be regulated only mildly. In the past and recently, problematic issues for the EU have included US exports of genetically modified crops into the EU as well as meat imports from American hormone-treated or -fed animals and chicken meat that was treated with chlorine.[6] On the part of the US, concerns have mostly been about EU lactic-acid washed meat, raw milk cheese and dairy imports into the States.[7] Both parties have according precautionary measures in place, but request each other to drop the various bans and ease regulatory practices and processes on other products.

Self-evidently these issues do not facilitate negotiations on the TTIP, particularly since they can be seen as a mere illustration of underlying differences in regulatory systems. Whereas the EU is generally thought to take a much more rigorous and precautious position on food safety and consumer protection, the US is often seen as more lenient and practical. Process-oriented risk governance thus now meets product-oriented risk governance in the current negotiations. Uncertainty and risks clearly present an issue or have at least become politicised and the question consequently arises whether and how these diverging positions could affect the TTIP and more generally international politics. It furthermore remains to be seen whether regulatory convergence is a necessary step towards improved cross-border risk governance or if there are other ways of enhancing systemic compatibility between the EU and the US.

This paper therefore sets out to investigate first, in the context of the GMO debate, how regulatory approaches differ between the EU and the US in the application of precaution in cases of uncertainty, and second, what impact these differences may have on the TTIP negotiations. The aim is to identify first, what both parties recognise as uncertain risk, second, how they respond to uncertainty, and third, how the (in)compatibility between these two risk governance systems could affect the TTIP. To these ends, the paper starts with an outline of its methodology, which includes a justification of cases, an explanation of the focus on precaution and the role of law and social science in the analysis. The next section then elaborates on precaution and the related precautionary principle. It gives a brief overview of historic developments and describes the role of precaution in EU and US law as well as with regards to the international dimension of the GMO dispute. The following section consists of the case analysis, in which both EU and US regulation of

5 Site European Commission: Transatlantic Trade and Investment Partnership (TTIP) Questions and answers.

6 Food safety 10-12-201.

7 Ibid.

MON810 and Pioneer 1507 are assessed. The findings about regulatory differences are then translated into possible impacts on the TTIP in a section that points out regulatory difficulties and incompatibilities to the TTIP negotiators. Finally, the paper summarises its findings in an overall conclusion and provides a future outlook into the domain of global risk governance.

2. Literature Review and Theoretical Background

The concept of precaution has been discussed broadly in the academic discourse on risk governance in light of uncertainty. It can however already be stated that scholars such as Van Asselt and Vos[8] [9], Wiener[10] and Linnerooth-Bayer, Löfstedt and Sjöstedt[11] have extensively discussed the notion of precaution in response to uncertain risks, sometimes on a cross-boundary level. In line with the idea of globalisation of risk, this paper emphasises the importance of conducting research that can shed light on cross-boundary risk governance. This is especially essential in the context of globalisation and increasingly expanding economic ties between countries. Products associated with uncertain risks - such as genetically modified organisms (GMOs), food treated in a certain procedure, toys made of material that include possibly irritating or harmful chemical components - may spread across political and legal systems through international trade.[12] This issue thus constitutes an inherent part of the ongoing TTIP negotiations. How can two different regulatory systems coordinate risk governance and control global and cross-boundary risks while at the same time establishing free trade with as few barriers as possible? And should they work towards regulatory coherence? Some scholarly literature already exists on the comparison of risk management between countries or institutions, like studies by Vogel and Lynch[13] or Alemanno[14] amongst others.

Focussing on potentially controversial issues with regards to risk governance convergence and compatibility between the EU and the US, this paper attempts to add value to existing

8 Van Asselt & Vos 2006.

9 Van Asselt & Vos 2008.

10 Wiener 2003.

11 Linnerooth-Bayer *et al*. 2001.

12 Van Asselt *et al*. 2013, p. 1-12.

13 Lynch & Vogel 2001.

14 Alemanno 2010.

academic literature through pointing out problematic areas and specific controversial issues that might be helpful for TTIP negotiators to address. It further holds that the discussion of both the long-ongoing transatlantic conflict over GMO regulations and the differing applications of precaution in view of uncertain risk can contribute significantly to develop a deeper understanding of transatlantic regulatory differences, which might facilitate the quest for making legal and political regulation of goods more compatible.

The transatlantic dispute about how strictly GMOs should be regulated has reached a certain significance due to its persistence. Going back to the 1990s, approaches have varied considerably.[15] While the US, since the Reagan administration, has treated GMOs essentially as equal to conventional products and has been rather inclusive of their use in food and feed as well as cultivation, the EU distinguished GMOs from conventionally grown crops from the beginning on.[16] These contradicting differences have led to disagreement due to repeated obstacles, restrictions and bans of American GMOs on the EU and Member State level: a conflict that has turned into a full-fledged dispute over the years, including trade conflicts and legal proceedings.[17] The relevance of the GMO debate to trade negotiations thus needs no further elaboration at this point.

However, there are a number of GMOs that have been more visible and significant in this context than others. The paper particularly sets out to assess the cases of the GMOs MON810 and Pioneer 1507. In the past, MON810 received a lot of media attention and fuelled public controversy over GMOs anew. It currently is one of only two GMOs that have been approved for cultivation in the EU and it is the only GMO intended for feed and food production that can legally be cultivated in the EU. Given this unique position, it exemplifies the full EU pre and post approval procedures. The case moreover presents an appropriate EU contrast to the US where the GMO was created and approved early on, in the 1990s. We therefore assume that MON810 neatly illustrates the regulatory differences between authorisation procedures in the EU and the US. In addition, it shows the disparities between the EU level (the European Commission) and the MS level with regards to the attitude towards the GMOs and the use of precaution respectively. The case of MON810 is further relevant for the case study of this paper as well as in the context of the general GMO debate, as a main underlying issue is the question of safeguard measures by EU MS and to what extent these are sufficiently 'science-based'. The process in which MS invoked the safeguard clause but were then rejected by EFSA implies

15 Pollack 2013, p. 1-2.

16 Ibid., p. 2-3.

17 Ibid., p. 3.

reluctance by the EU, particularly the Commission, to acknowledge the MS precautionary measures. MON810 thus exemplifies different layers within the EU and the diverging notions of what constitutes legitimate scientific information and about how and which uncertainty justifies precautionary measures. Despite a great volume of risk assessments and studies that have emerged, disagreement and regulatory differences between the EU and the US remain and make MON810 an ideal case for assessing the reasons behind this development and the chances or possibilities of successful harmonisation.

With regards to the selection of the Pioneer 1507 case, the rationale is a slightly different one. This paper holds that, as the crop was accepted by both US and EU systems for food and feed, but has not been authorised for cultivation in the EU since the application in 2001, it constitutes sufficient material to conduct an in-depth comparative case study, not only between systems across the Atlantic, but also within the EU. The recent ongoing political debate over the Pioneer 1507 approval for cultivation is a perfect opportunity to see what happens when EU MS take a different approach than the EU as a whole. It therefore provides a valuable case to investigate possible procedural and technical issues that hinder EU-US regulatory convergence and which could constitute problems in the TTIP negotiations.

The cases are evaluated with regards to first, where precaution -as defined in the following section- can be found or is applied. The analysis second focuses on what both parties recognise as uncertain risk and third, how they respond differently (or sometimes similarly) to uncertainty. Based on the findings, both case analyses finally draw tentative conclusions about the (in)compatibility of the EU and the US regulatory system and their respective application of precaution in order to foreshadow possible outcomes of the TTIP negotiations. As discussed by Van Asselt, Versluis, Fox and Vos[18] the interdisciplinary approach of this paper is intended to enable a more comprehensive analysis that grasps both legal regulatory settings and limits as well as political and social responses to uncertainty and related risks. The legal dimension of this paper will however mostly be limited to a focused analysis of related legal frameworks rather than legal interpretations of political action.

18 Van Asselt *et al*. 2013.

3. Precaution, Uncertainty and GMOs

One of the characteristics of a globalising world is the increasing interconnectedness of industrial activities between countries and continents.[19] Consequently, scientists, policy-makers, and eventually every ordinary person will be faced with new technologies and products whose implications are often unknown, such as GMOs.[20] Taken into account the inherent uncertainty associated with innovation, scientists are no longer able to sufficiently guide policy- and decisions-makers to make the correct, science-based decisions.[21] Given the limitation of scientific knowledge to answer all these questions concerning the scale of possible harm a product or activity may cause, and to respond to this, the concept of precaution emerged.[22] When speaking of precaution and uncertainty, literature often refers to the precautionary principle, which is considered to be an expression of precaution.[23] This principle has its roots in the German *Vorsorgeprinzip* (literally 'the principle of precaution'), where it became an important principles of environmental law in the 1970s.[24] Over the past three decades, it spread from Germany to European and international levels touching upon different policy fields.[25]

Despite the wide application of the precautionary principle, no unified accepted definition exists.[26] Instead, there are various versions of the precautionary principle, ranging from the simplest "better safe than sorry" to complex scenarios containing multiple elements.[27] Nevertheless, over time three elements of the principle have commonly been identified: a threat of harm, an uncertainty of impact and causality, and a precautionary response.[28] Furthermore, recent literature tends to distinguish between strong and weak versions of the precautionary principle.[29] In its strong form, the principle advocates for a complete prohibition of any activity or product which poses a danger to

19 Asselt & Bree, 2011, p. 401.

20 Holdway, 2009, p. 1.

21 Peel, 2004, p. 2.

22 Ibid.

23 Ibid.

24 Haritz, 2011, p. 80.

25 Santillo *et al*, 1999, p. 39-45.

26 Sachs, 2006, p. 33.

27 Sachs, 2011, p.1292; Gardiner, 2006, p. 33.

28 Fur & Kaszuba, 2006, p. 36. ; Gardiner; 2006, p. 36.

29 Morris, 2000, p. 1.

human health or the environment.[30] This ban can only be lifted if it is scientifically proven that the activity or product does not cause the expected harm.[31] At the other end of the spectrum, the weak version never comes in the form of a restriction or prohibition.[32] Instead, it can either take the form of a precautious attitude toward an uncertain activity or product or simply call for additional research in order to obtain more facts.[33] In conclusion, the precautionary principle is of a rather vague incoherent and troublesome nature, which opens the door to a wide scale of interpretation and possible misuse.[34]

With the remarkable growth of GM agriculture in the past decades, strong and often adverse reactions against it accordingly developed.[35] Issues of precaution are therefore closely linked to and highly visible in the GMO debate, particularly since the relentless backlash has its basis in uncertainty about the effects on health, safety and environment associated with GM crops.

3.1 EU Law

Precaution in the European Union as aforementioned can often be seen in the use of the precautionary principle. This principle is applied to a variety of risk issues when decisions need to be made and actions taken in situations that deal with uncertainty.[36] In other words, it is applied in order to deal with uncertain risks.[37] The principle was officially introduced in the 1993 Maastricht Treaty to form the basis of European environmental policy, and can now be found in Article 191(2) TFEU.[38] In 2000 the Commission issued a policy guideline to clarify when the precautionary principle was to be applied.[39] It was

30 Dana, 2009, p.1.

31 *Ibid.*

32 Gardiner 2006, p. 38.

33 Dana, 2009, p. 1.

34 Gardiner, 2006, p. 39-45; Haritz, 2011, p. 81.

35 Schmidt, 2005, A526.

36 Asselt & Vos, 2006, p.313-314.

37 *Ibid.*

38 See Article 191(2) TFEU (former Article 130r(2) of the EC Treaty) provides that the "Union policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Union. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay".

39 Communication from the Commission on the Precautionary Principle (Brussels, 02.02.2000 COM(2000) 1); see also Wiener, 2011, p.11.

noted that the precautionary principle could be invoked when there was a "potentially dangerous effects deriving from phenomenon, product or process" and "when scientific evaluation of the risk [...] makes it impossible to determine with sufficient certainty the risk in question".[40] Although the focus seems to be essentially science based, it was added that a criteria for decision-making could be the "level of risk the public considers appropriate".[41] Further clarification was also provided by the European courts, for example in the *Artegodan* case, where the court extended the application of the principle to public health and food safety.[42]

As regards to the GMOs, the principle is an element of the authorisation procedure for the use of GM food and feed, industrial processing and cultivation, explicitly addressed in the legal framework of the European Union. The framework originates from 1990 when the EU gained authority over agricultural biotechnology regulation, before which this was done rather permissively by the Member States.[43] The Council of Ministers adopted Directive 90/220/EEC on the Deliberate Release of Genetically Modified Organisms, which included a safeguard clause for the Member States to restrict or prohibit the use and/or sale of that product on its territory.[44] In the late 1990s the clause was invoked several times when concerns of potential adverse effects on health and environment arose among EU MS and the regulatory framework began to seem inadequate to deal with the new scientific development.[45]

Thus, to answer the growing European scepticism towards GMOs, the Directive was repealed in 2001 and replaced by Directive 2001/18, which now explicitly requires implementation in accordance with the precautionary principle.[46] In the following years, more regulations were added along the same line. Regulation 1829/2003 provides for the pre-marketing authorisation of GMO food and feed, whereas Regulation 1830/2003 lays

40 Communication from the Commission on the Precautionary Principle (Brussels, 02.02.2000 COM(2000) 1).

41 *Ibid.*

42 Joined Cases T-74/00 *Artegodan GmbH and Others v Commission of the European Communities,* §183; See also Sadeleer, 2009, p.149-150.

43 Vogel, 2012, pp. 47 & 74

44 Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms. OJ L 117, 08/05/1990, Article 16.

45 Christoforou, 2007, p. 199.

46 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. OJ L 106, 17/04/2001, Articles 1 and 4; See also Christoforou, 2007, p.199.

down rules on the traceability and labelling of GMOs as well as the traceability of food and feed produced from GMOs.[47]

The most interesting illustration of the role of the precautionary principle is the European Parliament and the Council Regulation 178/2002 laying down the General Principles and requirements of Food Law.[48] This Regulation manifests the application of the precautionary principle in two ways. First, Article 7 specifies the use of the principle where "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", thus linking the use of the principle to dealing with scientific uncertainty. Second, the principle is addressed in a wider context of risk analysis.[49] In accordance with Article 6 of the Regulation, EU risk management encompasses two phases; it shall take into account A) the results of risk assessment, and in particular, the opinions of EFSA and B) other factors legitimate to the matter under consideration and the precautionary principle.[50] This means that first the probability of the harm occurring is assessed through an expert evaluation of scientific facts, on the basis of which a political decision on the level of risk acceptable by the public should be taken.[51] Therefore, along with the ECJ interpretation, the decision to take precautionary measures can be justified when the results of a risk assessment are insufficient, inconclusive or imprecise, or in other words, an uncertain risk is established that is beyond the level accepted in society.[52]

Since the EU is not a federal construction comparable to the US, the accepted level of risk is not only decided at the Union level. In the ECJ case of *Gowan,*[53] the court interpreted the precautionary principle as a way to give the Commission wide discretion in deciding how

47 Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed [2003] OJ L 268; REGULATION (EC) No 1830/2003 OF THE EUROPEA N 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 [2003] OJ L 268/24.

48 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 [2002] OJ L31/1.

49 *Ibid.* Article 6, 7, 22; See also Sadeleer, 2009, p. 150.

50 *Ibid.* Article 6.

51 Sadeleer, 2009, p. 150-155.

52 Ibid. See to Case C-192/01, *Commission v. Denmark* , §52; see also Case E-3/00 *EFTA v. Norway*, §31. Case T-13/99, *Pfizer*, §162.

53 Case C-77/09 *Gowan Comércio Internacional e Serviços Lda V Ministero della Salute.*

and when to apply it in order to maintain a high level of protection of the environment as well as human and animal health. However, next to that, it follows from several ECJ cases that also the Member States may take a decision to invoke the precautionary principle as a response to scientific uncertainty, such as to a GMO authorisation.[54]

To that end, the European Directives and Regulations concerning GMOs contain various tools for the Member States. For example, Article 26a of Directive 2001/18/EC provides MS with the possibility to take appropriate measures to avoid the unintended presence of GMOs in other products, which can be used as a tool for creating protective practices for organic and conventional national agriculture.[55] More importantly, Article 23 of the same Directive lays down a safeguard clause according to which the MS are permitted to ban a GMO if they acquire "new or additional information ... 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".[56] The article holds that a MS "may provisionally restrict or prohibit the use and/or sale of that GMO as or in a product on its territory" if, based on the new information, that MS "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".[57] Upon invoking the safeguard clause, the allegedly new scientific information brought forward by the MS must then be assessed by EFSA and the Commission which may propose to the Council that scientifically groundless national bans be overturned.[58] In addition, Article 34 of Regulation 1829/2003 contains emergency measures, which can also be used where "the need to suspend or modify urgently an authorisation arises".[59]

The practice of precaution by the Member States will be concretely illustrated by the upcoming case studies of this paper. This is essential since it stands in clear contrast to the US federal system, where precaution is only taken at one level. Special attention will be paid to cultivation of GMOs, upon which the use of abovementioned tools has been the most

54 Case C-41/02 *Commission v Netherlands* [2004] §53 ; See also Alemanno, 2007, p. 12.

55 Directive 2001/18/EC Article 26. See also Communication from the Commission to the Council and the European Parliament - Report on the implementation of national measures on the coexistence of genetically modified crops with conventional and organic farming, COM/2006/0104 final.

56 *Ibid*. Article 23.

57 *Ibid*.

58 Pollack, 2013, p. 22.

59 Regulation (EC) No 1829/2003, Article 34.

frequent.[60] Moreover, the political struggle between the Commission and the Council (Member States) will be further examined. It can be pointed out that the Commission has pushed for a more liberal stance in GM approval by for example proposing four times to remove the national safeguard measures on cultivation.[61] The Council has each time responded to this by qualified majority rejection even though in legal terms the measures were not justified since they were not based on new or additional scientific information.[62] In order to deal with this hostility, the Commission has proposed a reform[63] on GMO cultivation in 2010, which after initial resistance from each sides of the debate has now resulted in a new compromised proposal.[64] The implications that this kind of multilevel risk governance might have for the TTIP agreement will be discussed later in this paper.

3.2 US Law

Precaution in American Law plays a role in both science-based risk assessment methods and protective regulatory actions.[65] The US has not explicitly embraced the precautionary principle in legislation or regulation action. It is often the case that US regulatory agencies decide on a course of action to protect public health, safety or the environment before science has resolved all the key questions about the suspected hazard and the effectiveness of prevention or mitigation efforts.[66] A "focus on serious and irreversible harms, [and] a wil ingness to regulate under conditions of uncertainty[...]" were "al firmly embedded into the US regulatory statutes".[67] The predominant aim of US statutory law

60 European Commission "Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee, and the Committee of the Regions on the Freedom for Member States to Decide on the Cultivation of Genetically Modified Crops," COM(2010)380 final, Brussels, 13 July 2010 p. 6

61 *Ibid.* p. 2

62 *Ibid.* p. 3

63 European Commission "Proposal for a Regulation of the European Parliament and of the Council amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory", COM(2010) 375 final, Brussels, 13 July 2010.

64 Council of the European Union; Interinstitutional File: 2010/0208 (COD) Brussels, 17 February 2014 (OR.en), Retrieved from http://m.greenpeace.org/greece/Global/greece/image/2014/gmos/reports_publications/Renationalisation_ 2014_Greek_Presidency_Proposal_for_19_Feb_Coreper.pdf; see also: Pollack 2013, p. 23, retrieved from http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2299609, last visited on 23 May 2014.

65 *Informing Regulatory Decisions: 2003 Report ti Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local and Tribal Entities* [Report]; Washington, DC: Office of Information and Regulatory Affairs, 2003.

66 *Ibid.*

67 Applegate, 2000, p. 420.

is to guarantee public health, safety and environmental quality, and if this is not possible, the reduction of risks.[68] Existing frameworks are the result of calls to place defined limits on potential risks[69] that will guarantee the protection of public health "*with an adequate margin of safety*".[70] [71]

The precautionary approach, albeit not an explicit US principle, has guided regulatory decision making for many years.[72] Accordingly, the 1950s Delaney Clause required the FDA[73] to ban outright food and colour additives that had been suspected of producing tumours in humans and laboratory animals.[74] [75] Furthermore, the notion of precaution has been incorporated in many American environmental statutes. One of their distinctive characteristics is the unwillingness to wait for clear evidence of harm before taking regulatory action.[76] The 1966 Endangered Species Act[77] likewise set the requirement for caution: the existence of potential irreversible harm to an "endangered", "jeopardised" or "threatened" species could result in making al development activities cease.[78] Precautionary elements are equally included in the National Environmental Policy Act (NEPA[79]), the most significant American environmental law.[80] American courts in the 1970s often interpreted US regulatory statutes in a way that endorsed the precautionary approach inherent to risk

68 Charnley, Elliott, 2002, 1036.

69 *Ibid*, p.369.

70 42 U.S.C. § 7409(b)(1) Clean Air Act, available at www.epw.senate.gov/envlaws/cle anair.pdf, last visited on 24 May 2014.

71 42 U.S.C. § 7409(b)(1) the Clean Air Act.

72 Wiener, 2011, p.369.

73 Vogel, 2012, p. 253.

74 Wiener, 2011, p.369.

75 Federal Food, Drug and Cosmetic Act, available at http://www.fda.gov/regulatoryinformation/ legislat ion/federalfooddrugandcosmeticactFDCAct/default.htm, last visited on 24 May 2014; See also Federal Food, Drug, and Cosmetic Act; 21 U.S.C.A, §§ 409 (c)(3)(A), 706 (b)(5)(B), and 512(d)(1)(H).

76 Vogel, 2012, p. 253.

77 Endangered Species Act 1966, available at http://www.nmfs.noaa.gov/pr/laws/esa/text.htm, last visited on the 24th of May 2014.

78 Vogel, 2012, p. 253.

79 The National Environmental Policy Act of 1969, available at http://energy.gov/nepa/downloads/ national- environmental-policy-act-1969, last visited on 24 May 2014.

80 Caldwell, 1998, p. 203.

assessment procedures.[81] Through cases such as *Reserve Mining*[82] [83] and *Ethyl Corp. v U.S. Environmental Protection Agency* the Supreme Court expanded precautionary standards and established regular involvement of regulatory agencies like the EPA.[84] [85] Decisions included the ruling that the "wil endanger" standard is precautionary in nature and does not require proof of actual harm before regulations are appropriate.[86] The legal reasoning holds that some scientific evidence can be sufficient for environmental regulation when there is significant risk.[87] The burden of proof was consequently put on the regulators who had to demonstrate that an environmental risk was of sufficient importance to justify regulating it.[88] Before the 1980s US regulatory agencies considered risk assessment a "highly judgmental and largely qualitative exercise".[89]

The need for risk regulations to be backed up by scientific risk assessments dates back to the 1980s.[90] The Supreme Court's *Benzene* decision turned away from the precautionary policy established in the *Ethyl* ruling and substituted the latter with a fact-based principle focusing on the extent of risk.[91] The *Benzene* decision established a workplace standard for benzene exposure[92] that allowed for regulation only if exposure posed a "significant risk of material health impairment".[93] [94] Although the court did not define "significant risk of material health impairment", the decision strongly implied that some form of the quantitative risk assessment was necessary as a basis for deciding whether a risk is great enough to deserve regulation.[95]

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81 Vogel, 2012, p. 254.

82 Bartlett, 1980, p.438.

83 Vogel, 2012, p. 254.

84 *Ibid.*

85 *Ibid.*

86 *Ethyl Corp. v EPA* 24 ELR 21591 No. 93-1768, 25 F.3d 1241/(4th Cir., 06/01/1994).

87 Ricci, 2006, p. 11.

88 Vogel, 2012, p. 254.

89 Jasanoff, 2003, p.231.

90 Vogel, 2012, p. 256.

91 *Industrial Union v American Petroleum Institute* 448 US 607.

92 Vogel, 2012, p. 256.

93 Wiener, 2011, p.369.

94 Schwartz, 1981, p. 299.

95 Wiener, 2011, p.369.

Around the same time, the White House Administration formulated its federal policy on genetically modified food and agriculture, which consists of three principles.[96] First, the emphasis lies exclusively on the final GM product rather than on the process of applying GM technology. Therefore, the US approach can be determined as product-based.[97] Second, 'scientific risk' plays a major role in US decision-making on regulatory action and barring technologies.[98] Only when there is a verifiable and real scientific risk, GM technology cannot be introduced and integrated.[99] Third, there is a general US American perception of GM products as continuum alongside other agricultural innovations.[100]

The three agencies – FDA, EPA and USDA, have constructed a related regulatory framework. Its distinctive characteristics are its comprehensive nature, its composition as a "mosaic of existing federal law" and the recognition of many products obtained with genetic engineering.[101] The FDA was the first governmental agency to incorporate risk-assessment into the decision-making[102] and has extended its practice from substances added or contaminating food to directly added food ingredients in defiance of the "zero-risk" requirements of the Delaney Clause.[103][104] The agency has thus moved away from the three principles outlined by the White House Administration during the 1980s and set a mandatory pre- market consultation program especially for products created with the help of bioengineering.[105] Additionally, the FDA agency has now approved voluntary labelling of GM content.[106]

The Environmental Protection Agency (EPA) is the second agency that shares the responsibility of supervising GM products.[107] On the basis of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA[108]), the EPA's Office of Pesticide Programs is entrusted

96 Marden, 2003, p. 733.

97 *Ibid.*, p.734.

98 Vogel, 2012, p. 257.

99 Marden, 2003, p.784.

100 *Ibid.*

101 *Coordinated Framework for Regulation of Biotechnology.* Office of Science and Technology Policy, Executive Office of the President, Office of Science and Technology Policy (OSTP), 1986; 51 FR 23302, From now on named as OSTP. Retrieved from www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf, last visited 19 May 2014

102 Rodricks *et al.*, 1987, p.308

103 *Ibid.*, p.308

104 Vogel, 2012, p. 261.

105 Marden, 2003, p.785.

106 *Ibid.*

107 *Ibid.*, p. 776.

108 Federal Insecticide, Fungicide, and Rodenticide Act, available at http://www.epa.gov/oecaagct/lfra.html, last visited on 24 May 2014.

with the protection of the environment and is enabled to oversee the manufacturing, sale and use of plant pesticides and related organisms. In contrast to the FDA, EPA remains committed to the three characteristics that shape the White House approach.[109]

Similarly to the FDA, the US Department of Agriculture (USDA) approach adhered to the principles shaped by the White House.[110] It started with a position that was more precautionary than the Coordinated Framework and the policy statements. However, it eventually evolved and shifted towards a more risk-based approach. The USDA was appointed by the Coordinated Framework to supervise the introduction of GM plants into agriculture and their transport across the United States.[111] The USDA, as represented by its APHIS department, is in charge of regulating plants, plant pests and animal biologics and biotech products intended for agricultural use.[112] The APHIS oversees the release of genetically engineered plant pests, but since there are no test requirements incorporated in the PPA, a Code of Federal Regulations (CFR) was issued.

If a product intended for release satisfies al the 'performance standards' and 'eligibility criteria', it may be tested in field trials and may be moved within federal territory.[113] In this notification approval process the APHIS firstly evaluates the available information submitted by the applying company and that derived from "other sources" and, secondly, notifies the competent authorities of the federal State before a decision on whether to al ow "the notification" is made.[114]

A second responsibility of the APHIS is the determination of non-regulated status after having granted the notification or permit. After the field testing has been concluded, the company may submit a petition for determination of non-regulated status if the information gathered suggests that the tested plant pesticide is not harmful to the environment.[115] A petition must be filed to this purpose and be submitted to APHIS.[116] Any reception of a petition must be notified by APHIS in the Federal Register.[117]

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109 Marden, 2003, p.784.

110 *Ibid.*

111 *Ibid.*, p. 768.

112 OSTP.

113 See Chapter Title 7, Subtitle B Chapter III Part 340 of the CFR.

114 The White House, Case Study No. II: Bt-MAIZE, p. 9.

115 §340.6 CFR.

116 See requirements listed under §340.6 CFR.

117 *Ibid.*

3.3 The International Dimension of the GMO Dispute

For the international dimension of the regulatory divergence between the EU and the US, the role and effectiveness of the World Trade Organisation (WTO) in solving the transatlantic trade dispute regarding GMOs must be scrutinised. It is important to note that the EU and the US constitute the two biggest economies in the world.[118] Consequently, their trading relationship amounts to the largest bilateral trade relation worldwide.[119] Not only do the EU and the US benefit greatly from their economic partnership, but it moreover contributes to a more open and efficient world trade system.[120] Thus, it is self-evident that the regulatory dissimilarities between the two superpowers hinder transatlantic trade relations and expose their economies to considerable losses.[121] Throughout the years these dividing regulatory differences have led to considerable tensions which eventually escalated into a legal dispute.[122] In 2003, the US together with Canada and Argentina decided to sue the EU for its regulatory barriers concerning GMO authorisation.[123] As both the EU and the US are WTO members, the case was brought before the WTO dispute settlement body as envisaged in *The Understanding on Rules and Procedures Governing the Settlement of Disputes*.[124]

The *EC-Biotech case* concerned the delays of authorisation of GMOs on the EU market from 1998 to the time of establishment of the Dispute Settlement Panel in 2003.[125] Particularly, three issues were at stake. First, non-compatibility with the WTO rules of the moratorium by which the EU delays GMOs approval until a more stringent regulatory process is put in place.[126] Second, individual delays in the approval process for specific GMOs in the Member States.[127] Third, MS (Austria, France, Germany, Greece, Italy, Luxembourg) reliance on the safeguard clauses and consequent national bans of

118 The official webpage of the European Commission, DG Trade. Retrieved via http://ec.europa.eu/trade/policy/countries-and-regions/countr ies/united-states/.

119 Breuss, 2005, p. 4.

120 Ahearn, 2006, p. 1.

121 *Ibid.* p. 3.

122 Pollack, 2013, p. 5.

123 European Communities-measures affecting the approval and marketing of Biotech products. Reports of the Panel WT/DS291/R, WT/DS292/R, WT/DS293/R, 29 September 2006, Para 1.1.

124 Annex 2 of the WTO Agreement: Understanding on rules and procedures governing the settlement of disputes.

125 Measures affecting the approval and marketing of Biotech products[Reports], 2006.

126 *Ibid.* Para 4.132.

127 *Ibid.* Para 4.133.

GMOs despite authorisation at EU level.[128] The complainants claimed that aforementioned actions violated the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS), Technical Barriers to Trade Agreement (TBT), and General Agreement on Tariffs and Trade (GATT).

The WTO found that the EU had violated WTO rules concerning undue delays in the completion of the approval procedures for the specific GMOs.[129] Furthermore, regarding the MS safeguard measures, it was ruled that these bans were inconsistent with WTO rules, since necessary scientific evidence for potential harm was not provided as defined in the SPS Agreement.[130] Following this, the Dispute Settlement Panel recommended the EU to ensure conformity of the Member States safeguard measures with the SPS agreement.[131] The EU declared its intention to bring the EU rules in conformity with the WTO rules. However, it requested more time in order to do so due to complexity and sensitivity of the issue.[132] The case has not fully been solved.

In light of the above, the WTO dispute settlement system has proven to be ineffective in the case of the EU-US dispute over the GMOs. The pressure put on the EU by the WTO's decision in the *EC- Biotech case* did not contribute to the changing of the fundamental regulatory procedures for GMO authorisation on the EU market.[133] Although some regulatory developments both in the EU and the US have occurred, this did not improve the situation much. First, the EU continuous to be more rigid and precautious than the US.[134] Second, the EU's and the US's different domestic policies, regulations, and standards of consumer and environmental protection which lie at the heart of the trade conflict between the EU and the US remain unchanged.[135] Furthermore, the economic, social and political dimensions of this trade dispute do not facilitate reaching an agreement.[136] In this respect, EU Member States' negative attitude toward GMOs, which is reflected by bans of GMOs based on the 'safeguard clauses', demonstrates a particular problem.[137]

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128 *Ibid.* Para 4.134.

129 *Ibid.* Para 8.1 - 8.63.

130 *Ibid.*

131 *Ibid.* Para 8.64.

132 Negi, 2007, p. 1.

133 Prevost, 2007, p. 100; See also Pollack; 'A Truce in the Transatlantic Food Fight', 2013, p. 6.

134 Pollack, 2013, p. 19.

135 Ahearn, 2006, p. 1.

136 *Ibid.*

137 Pollack, 2013, p. 20.

Additionally, the *EC-Biotech case* clearly revealed the limitations of the WTO. The WTO as an international organisation is not capable of adequately addressing non- economic factors such as the precautionary principle.[138] As a result, the transatlantic trade dispute between the EU and the US remains unsolved.

3.4 A Working Definition

The previous sections have demonstrated the main regulatory differences between the EU and the US with regard to risk regulation and the application of the precautionary approach in the case of GMOs. For the purpose of this paper it is thus crucial to have a clear definition of what precaution means, when assessing the latter in the context of EU and US regulatory systems. However, the difficulty with the concept of precaution, including the precautionary principle, is that there is no clear, uniform definition of it. To facilitate the analysis, this paper therefore outlines three notions of precaution. It first recognises precaution as any actions in response to uncertainty that seek to resolve the uncertainty or prevent the possibility of harm derived from these and related uncertain risks. This rather broad definition includes, amongst others, risk assessments, requests for clarifications or revisions. Nevertheless, a few further distinctions must be made with regards to the particular characteristics of the EU and the US and concerning the precautionary principle. While notwithstanding the previous definition, the following two are additionally used.

With reference to the EU system, precaution is often expressed in the precautionary principle that is explicitly mentioned in the legal framework for GMO authorisation. But -as illustrated earlier- it functions at two levels. The working definition of the precautionary principle on the EU level shall thus be related to the discretionary power of the Commission: the paper acknowledges the use of the precautionary principle in a ban or a partial authorisation or restriction of GMOs for the sake of the environment, human and animal health.

The third and final working definition for the identification of precaution in the case studies concerns the MS level. Here, in turn, this paper has decided to recognise the precautionary principle whenever a MS invokes the safeguard clause or applies emergency measures and practices to prevent unintended consequences of GMOs or undesired GMO presence in the MS's national market and products. It has to be noted, however, that the difficulty with the safeguard clause is the actual motivation of the MS to invoke the latter.

138 Henckels, 2006, p. 304.

Reasons to draw up precautionary actions may not be limited to the legal framework of the EU and the protection of human health and the environment. Other, political factors could also play a role, such as the protection of national markets or local producers and firms. Although the in-depth assessment of the actual motivation behind MS action is beyond the scope of this paper, this study tries to critically assess precaution on the MS level in light of whether measures are actually based on new scientific evidence. An extensive debate on the specific political motives behind precautionary measures does however not lie within the limits of this paper.

As discussed in the previous sections, the US does not explicitly apply the precautionary principle, but there is rather the notion of a 'precautionary approach'. The concept of precaution as a response to uncertainty is thus very vague in practice. For the purpose of this paper, the aforementioned broader definition of precaution is used to identify precaution on the part of the US. These definitions help to illustrate the differences in regulatory and practical approaches to uncertainty in the EU and the US in a more exhaustive way, as they take into account particular EU and US characteristics while at the same time remaining open enough to allow for generalisability and interpretation.

4. Case Analysis: The Complexities behind GMOs

GMOs have been giving rise to tension between the EU and the US for quite some time now. This tension is exemplified by the large drop of US to EU corn exports in 1997 and 1998 which coincides with the introduction of GMOs on the US market.[139] The wider dispute has been going on for over two decades and now, in light of the TTIP negotiations, has been fuelled anew.[140] MON810 is a genetically modified maize strain, developed by the US company Monsanto. This maize-line is an example of an insect-protected GM crop. This effect is achieved by inserting a gene (taken from the bacterium *Bacillus thuringiensis*) which helps the crop to produce a specific protein (in this case Bt toxin). This protein is poisonous for Lepidoptera-insects, such as the European Corn Borer. Pioneer 1507, sometimes referred to as TC 1507, is also a genetically modified maize line. It was developed by the companies Mycogen Seeds c/o Dow AgroSciences LLC and Pioneer Hi-Bred International. Pioneer 1507 is also an insect- protected crop through the insertion

139 EU-U.S. High Level Working Group on Jobs and Growth Response to Consultation by EuropaBio and BIO *s.d.*

140 Pollack 2013, p. 1-2.

of a gene. This gene is taken from the bacterium *Bacillus thuringiensis* as well and, not-surprisingly, has the same effect in that it allows the crop to produce the Bt toxin- protein, thus protecting it from certain insects.[141]

In the following sections this paper analyses both cases in terms of the regulation process and the application of precaution. However, particular attention is devoted to the regulatory process in the EU, as claims of heightened risk averseness in the EU and the involvement of the Member State level make GMO regulation much more complex than it is in the US.

4.1 MON810 in the EU

When analysing precautionary measures in the regulatory process of MON810 in the EU, it is crucial to distinguish between precaution on two levels. First, at the Community level: here, precaution is predominantly conducted through EFSA's repeatedly updated risk assessments and the delivery of scientific opinions upon requests from the Commission with regard to the application of new GMOs, the invocation of safeguard measures as well as on post-market monitoring.[142] Second, on the national level MS invoke precautionary measures that are, in most cases, legally installed in the safeguard clause set out in Article 23 of Directive 2001/18/EC or the emergency measures contained in Article 34 of Regulation (EC) No 1829/2003.[143] For the case at hand, it can be stated that approval at the Community level proceeded rather smoothly, whereas at the MS level, considerable opposition was triggered especially with regard to the cultivation of MON810. Furthermore, the case of MON810 exemplifies diverging views between the Commission and EFSA on one side and MS on the other, with regard to what constitutes legitimate scientific evidence to justify precautionary measures.[144]

The regulatory process of MON810 in the EU started in 1997, when Monsanto submitted a notification to the competent French authority, seeking approval to place its GM maize on the market under Directive 90/220/EEC for growing, import and seed production among other purposes.[145] Later that year, Monsanto submitted a notification for its use in food

141 Site GMO compass: Maize 1507.

142 EFSA Scientific Opinion EFSA Journal 2012;10(12):3017, EFSA Scientific Opinion EFSA Journal 2012;10(5):2705, EFSA Scientific Opinion EFSA Journal 2012;10(4):2610.

143 European Commission 'Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee, and the Committee of the Regions on the Freedom for Member States to Decide on the Cultivation of Genetically Modified Crops,'(Brussels, 13.07.2014 COM), p. 6.

144 Wickson & Wynne 2012 p.323.

145 EFSA Opinion. The EFSA Journal (2006) 338, p.5.

and food ingredients under Regulation (EC) No 258/97, which governs the authorisation procedure for genetically modified foods.[146] The French Ministry of Agriculture deemed the notification to be sufficient and consequently forwarded it with a favourable opinion to the Commission which in turn forwarded it immediately to the competent authorities of all MS, giving them the possibility to raise objections.[147] Immediately, several MS demanded additional labelling requirements as well as additional product information for international maize traders.[148] As these requests implied a desire to limit remaining risk and reduce uncertainties through more transparency, they could be seen as an expression of precaution as understood by the working definition of this paper. The various objections, moreover, indicate a considerable degree of varying risk aversion among the MS who were unable to reach agreement. Consequently, the Commission had to reach an agreement and established a committee of MS representatives, following the procedure laid out in article 21 of the Directive.[149] In the process of reaching an agreement, the Commission sought the opinion of relevant scientific committees, foremost the Scientific Committee on Plants, which was asked to consider whether there were any reasons to believe that the placing on the market of MON810 was likely to cause adverse effects on human health and environment.[150] In its overall assessment, the committee concluded after examining the information and data provided in the dossier that there was no reason to believe that MON810 is likely to cause adverse effects on human or animal health and the environment.[151] Relying on the scientific opinion and the opinion of the committee established under Article 21 of Directive 90/220/EEC, the Commission adopted Decision 98/294/EC, giving its consent to the placing on the market of MON810 under Directive 90/220/EEC.[152]

As the approval had been concluded at Community level, the next step was the introduction of MON810 at Member State level. The MS, however, soon displayed resistance by invoking safeguard measures against MON810. Austria was the first to impose a national ban on MON810 in 1999, thus effectively preventing its commercial release within

146 EFSA Opinion of the Scientific. The EFSA Journal (2004) 49, 1-25.

147 Tosun 2013, p. 69.

148 Commission Decision 98/294/EC, 22 April 1998, OJ. OJ L 131/32.

149 Ibid.

150 Scientific Committee on Plants Opinion of the Scientific Committee on Plants Regarding the Genetically Modified, Insect Resistant Maize Lines Notified by the Monsanto Company. 1998.

151 Ibid.

152 Commission Decision 98/294/EC, 22 April 1998, OJ. OJ L 131/32.

Austrian territory.[153] Soon, an increasing number of MS openly declared their opposition to further GMO authorisations. This development resulted in the de-facto moratorium on new GMO authorisation and a period where precaution was arguably exerted in its most restrictive form.[154]

After the revision of EU GMO legislation, Monsanto Europe notified MON 810 maize to the Commission in July 2004, as an 'existing product' on the basis of Article 20 of Regulation 1829/2003.[155] The initial authorisation of MON810 expired in April 2007, but the crop remained on the market until a decision on the new application was taken.[156] In July 2009, EFSA delivered its scientific opinion on the applications for renewal of authorisation for the continued marketing of MON810 for various purposes under Regulation 1829/2003.[157] EFSA exerted precaution in the form of a comprehensive scientific risk assessment, which included *inter alia* a molecular characterisation of the inserted DNA, a comparative analysis of agronomic traits as well as an environmental impact assessment and a post-market environmental monitoring plan.[158] When delivering its scientific opinion, consisting of 84 pages, EFSA also considered the additional information supplied by the applicant, the scientific comments submitted by Member States as well as relevant information published in scientific literature.[159] Notwithstanding the thorough and extensive risk assessment, EFSA once more concluded that MON810 and derived products are unlikely to have any adverse effect on human and animal health in the context of the intended uses.[160] EFSA's GMO panel further held that the available information for MON810 addresses the scientific comments raised by MS and that MON810 is as safe as its conventional counterpart with respect to potential effects on human and animal health, thus making it unlikely to have any adverse effect on the environment.[161]

153 GMOs in Europe: A Status Report *s.d.*

154 Morris & Spillane 2010. p. 361.

155 Regulation 1829/2003/EC, 22 September 2003, OJ L 268

156 Monsanto Company (2007) Application for renewal of the authorization for continued marketing of existing MON 810 maize products that were authorized under Directive 90/220/EEC (Decision 98/294/EC) and subsequently notified in accordance to Article 20(1)(a) of Regulation (EC) No 1829/2003 on genetically modified food and feed.

157 EFSA Scientific Opinion. The EFSA Journal (2009) 1149, p.1.

158 Ibid. p.2.

159 Ibid. p.3.

160 Ibid. p.56.

161 Ibid.

Despite EFSA's repeated positive scientific opinion, various MS invoked national safeguard measures against MON810 cultivation. In 2004, Austria maintained its earlier ban under article 23 of Directive 2001/18. It was followed by cultivation bans, invoked by Hungary and Greece in 2005, Luxembourg in 2006 and France in 2007, all of which were based on Article 23 of Directive 2001/18 and in the case of France additionally pursuant to emergency measure set out in Article 34 of Regulation 1829/2003.[162] Moreover, Poland banned cultivation of MON810 in 2005 under Article 16 of the EU's Seeds Directive 2002/53/EC, thus effectively banning more than half of the available MON810 varieties.[163] Similarly, Romania announced a cultivation ban on MON810 in 2008, with the intention to install it on the same legal grounds as the French measure.[164] In 2009, Germany refused to approve the reapplication of MON810 and instead instituted a ban pursuant to the safeguard provisions in Article 23 of Directive 2001/18 and Article 34 of Regulation 1829/2003.[165] In each instance, EFSA and the relevant scientific committees found no scientific justification for Member State bans.[166] On the contrary, EFSA's GMO panel concluded in all cases that there was no new science-based evidence presented that would invalidate the previous risk assessments carried out on maize MON810. The panel further concluded that there was no specific scientific evidence, in terms of risk to human and animal health or the environment that would support the notification of an emergency measure or the invocation of a safeguard clause.[167] This development hints that safeguard clauses are being invoked not merely as a precautionary measure on the basis of new scientific information but seemingly on the basis of allegedly new evidence motivated by ethical values inherent to the framing and interpretation of the studies. However, it remains unclear if national safeguard measures are to a certain extent deliberately informed by political motives or whether the different views regarding their legitimacy stem from different interpretations of uncertainty that do not fit the EFSA's narrow definition of 'new scientific evidence'. In this context, scholars

162 Stephenson 2010, p.307.

163 GE cultivation bans in Europe *s.d.*

164 Ibid.

165 Stephenson 2010, p.308.

166 Bodiguel & Cardwell 2010, p.149.

167 EFSA Scientific Opinion EFSA Journal 2013;11(9):3372, EFSA Scientific Opinion. EFSA Journal 2013;11(9):3371, EFSA Scientific Opinion. EFSA Journal 2012;10(9):2877, EFSA (2012) Scientific Opinion EFSA Journal 2012;10(5):2705, EFSA Scientific Opinion The EFSA Journal (2008) 891, 1-64, EFSA Scientific Opinion The EFSA Journal (2008) 850, 1-45. EFSA Scientific opinion. The EFSA Journal (2008) 757, 1-12. EFSA Scientific opinion The EFSA Journal (2008) 756, 1-18, EFSA (2006) Opinion. The EFSA Journal (2006) 411, 1-26.

have already argued that risk assessment in the context of innovation is a political act.[168] Unfortunately, a comprehensive analysis of all individual safeguard measure that have been invoked against MON810 is beyond the limitations of this paper.[169] This paper therefore focuses on the example of the French safeguard measures, which brilliantly illustrate the tension and ambiguity at the science-policy interface.

In October 2007, the French government enacted a precautionary measure, temporarily suspending the cultivation of MON810 within its territory.[170] Following the suspension, the French Ministry of Ecology formed a temporary Committee (CPHA) with the aim of determining the effects of MON 810 on the environment.[171] One month after its creation, the CPHA handed in a report.[172] In a response to this report, the French government informed the public that the Committee had 'serious doubts' about the impacts of MON810.[173] Surprisingly, twelve out of fifteen scientists from the CPHA opposed the French government's announcement, stating that first, their report was only a draft and second, the words 'serious doubts' were not present in the report.[174] Despite the scientists' opposition, France invoked the precautionary principle and formally ordered the ban on the cultivation of MON810 under the safeguard clause (Art. 23 of Directive 2001/18/EC); a few days later also under the emergency measure (Art. 34 of Regulation 1829/2003).[175] The new information package about the effects of MON810 found by France was forwarded to EFSA. EFSA fully dismissed the French claim and confirmed that information submitted by France did not present new evidence that would invalidate previous risk assessments of maize MON810.[176] Thus, the invocation of the safeguard clause and the emergency measure by France were considered unjustified.[177] Following EFSA's opinion, Monsanto Europe brought a case for annulment of the French ban before the *Conseil d'Etat*.[178] The

168 Marjolein B.A. van Asselt *et al.* 2013, p. 272.

169 Further research needs to be conducted regarding the politicisation of precautionary measures as well as the motives of the EU MS who invoked the safeguard clause against MON810

170 Tosun 2013, p 70.

171 Morris & Spillane 2010, p. 363.

172 Ibid.

173 *Ricroch et al 2010, p.2.*

174 Ibid.

175 Bodiguel & Cardwell 2010, p.149.

176 EFSA Scientific Opinion The EFSA Journal (2008) 850, p. 2.

177 Ibid.

178 Kershen 2014, p. 2.

Court stayed proceeding and referred the question to the ECJ under Art. 167 TFEU.[179] The ECJ ruled that the French ban was illegitimate since in order to invoke the precautionary principle there must be a significant scientifically verified risk that clearly jeopardises human health, animal health or the environment.[180] After the ECJ ruling, the *Conseil d'Etat* confirmed the illegitimacy of the French measure.[181] A few months later, France provided the European Commission with a new piece of proof in support of its request for the prohibition of MON810.[182] EFSA rejected France's claim once more.[183] Since then, the French ban on MON810 cultivation has remained in place.

An analysis of the exact motives behind the French invocation of the safeguard clause appears intricate and is beyond the limitations of this paper. Nevertheless, the question is raised to what extent the French measure demonstrated an act based on scientific risk assessment with the purpose of protecting human health and the environment, or rather a political act. In light of EFSA's extensive and balanced scientific opinion, it was concluded that France had no new scientific argumentation to support its ban on MON810 cultivation. This suggestion was reinforced and reflected by scientists' opposition to the French interpretation of the CPHA report and by the ECJ and the *Conseil d'Etat* judgements, which clearly held that the French ban was illegitimate. Notwithstanding the considerable resistance, the French ban on MON810 cultivation is still in place. In this respect, some scholars argue that the French decision was rather of a political nature,[184] thereby driven by the political agreement between the French government and environmentalists.[185] Similarly, Wickson and Wynne, in their study on the entanglements of science and ethics in the regulation of MON810, rightly argue that there is an inherent ambiguity in the framing and interpretation of risk-based science.[186] This ambiguity is amplified in its significance when uncertainties are high, as is the case for the release of GMOs into complex ecological systems.[187]

179 Cases C-58/10 to C-68/10 *Monsanto and Others* [2011] ECR I-7763, para 38.

180 Ibid. para. 76.

181 CE. 1 August 2013, Association génerale des producteurs de maïs (AGPM) et autres, Nos 358103,358615,359078, para 6-23.

182 Ricroch et al 2013, p. 498.

183 EFSA Scientific Opinion. EFSA Journal 2012;10(5):2705, p. 2.

184 Ricroch et al 2013, *p. 499*.

185 Morris & Spilane 2010, p. 364.

186 Wickson & Wynne 2012

187 Ibid.

Being qualified as scientifically ungrounded through EFSA, the Commission attempted on four occasions to overturn national bans.[188] However, the Commission faced in each case considerable opposition in the Council of Ministers where a qualified majority of the MS voted against the Commission's decisions to order the waiving of national bans.[189] With the Commission's hands being tied, by early 2013, eight EU Member States had retained bans on the cultivation of one or both of the two approved GM crops (MON810 & Amflora Potato).[190] The controversy over national safeguard measures is particularly interesting with regard to the ongoing TTIP negotiations, as scientifically groundless national safeguard measures constitute a very contentious issue between the EU and the US, which culminated in the *EC-Biotech* case.[191] What is particularly striking is that MS can still resist harmonisation and maintain scientifically unjustified bans under the label of the safeguard clause. In order to solve the protracted status quo, the Commission has proposed an "opt-out clause" for MS with regards to GMO cultivation.[192] MS would then be given the possibility to adopt measures restricting the cultivation of GMOs in all or part of their territory on the basis of grounds such as ensuring co- existence, or more generally political or economic motivations.[193] Despite receiving support from more than 20 EU Member States, it was successfully blocked by a minority of bigger states that feared that the proposal would conflict with the internal market and WTO rules.[194] The proposal has been described as a "grant bargain," whereby Member States might become more lenient towards the authorisation of GM foods at the EU level, in exchange for the possibility to legally ban all or particular GMOs from cultivation in their territories.[195] The proposal is currently being revised and it remains to be seen whether MS will be given the possibility to opt out of GMO cultivation on grounds other than new or additional scientific information invalidating the prior risk assessment.[196] This ultimately raises another

188 Pollack 2013, p. 22.

189 European Commission 'Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee, and the Committee of the Regions on the Freedom for Member States to Decide on the Cultivation of Genetically Modified Crops,' (Brussels, 13.07.2010 COM), p.2.

190 Pollack 2013, p. 22.

191 Prevost 2007, p.71.

192 European Commission 'Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee, and the Committee of the Regions on the Freedom for Member States to Decide on the Cultivation of Genetically Modified Crops,' (Brussels, 13.07.2010 COM), p.6.

193 Ibid.

194 More than 20 Member States support the Presidency's GMO compromise proposal *s.d.*

195 Philips 13-06-2010, p.12.

196 Council of the European Union; Brussels, 17 February 2014, 2010/0208 (COD).

question that remains open with regard to the ongoing TTIP negotiations, namely whether Biotechnology companies will find new ways to challenge illegitimate national SPS measures. One such tool could be the proposed ISDS provisions that are expected to be incorporated in the agreement and will be discussed in more detail later on in the paper.

4.2 MON810 in the US

The GM maize line MON810 was formally subject to the jurisdiction of USDA's Animal and Plant Health Protection Service (APHIS) responsible for regulating the plant and the EPA's Biopesticides and Pollution Prevention Division (BPPD) that had oversight over the pesticide substance produced in the plant. After both agencies had concluded their assessment of MON810 the third main US regulatory agency, the FDA, was also requested to submit its opinion in order to finalise the approval process. The approval of MON810 for release into the environment in 1995 and for placing on the market and use in food and feed in 1996 was thus the result of an interagency assessment and management process.[197] The registration of MON810 expired in 2001 and it had to be re-registered by the EPA subject to new regulatory acts, such as the Food Quality Protection Act (FQPA).[198] Overall the case of MON 810 demonstrates that the US is responsive to uncertainty and employs precautionary actions. However, compared to the EU, US regulators were able to act much quicker, even before uncertainty was resolved and bases its decisions on historical experience and a cost-benefit-analysis.

In the 1990s the first assessment of MON810 was undertaken by APHIS which among other issues, looked at the risk of "imparting plant pathogenicity" and the impact on conventional commodities, non-target organisms and the biodiversity in general.[199] At this stage a precautious stand can be seen as regulators did not directly authorise MON810, but only issued a temporary field trial permit for further testing of the GM crop between 1992 and 1996.[200] MON810 was thus declared a regulated article under the CFR. In 1995, Monsanto submitted a petition for determination of 'non- regulated status' of MON810 and other BT-maize lines.[201] APHIS found the submitted data to be insufficient to attest a required level of safety and accordingly requested further information and clarification of

197 ISAAA website: MON1445 *s.d.*

198 The White House Case Study No. II: Bt-MAIZE, p.5.

199 Ibid., p.31.

200 §340.4 CFR Ibid., p.31.

201 APHIS Draft Combined Documents: Notices Federal Register Vol.61:52, Friday, March 15 1996.

data.[202] Monsanto consequently withdrew the petition. This refusal by APHIS corresponds to the working definition for precaution, as uncertainty was identified and addressed through making authorisation conditional upon more scientific evidence. In January 1996, Monsanto filed and submitted a new petition. This petition was published and the stakeholders were enabled to put forward comments.[203] APHIS reviewed the additional data that had been submitted and conducted an Environmental Assessment under the NEPA concluding that "no significant impact on the environment (FONSI)" was present.[204] The petition was finally accepted and MON810 was granted 'non-regulated status' under Title 7 Part 340 CFR in March 1996.[205]

The EPA, carrying out its responsibility to assess and regulate plant pesticides, based its judgment for the approval of MON810 on its own hazard identification and assessment and a risk-benefit analysis by following the requirements contained in the FIFRA and the FFDCA statutes. MON810's endotoxin had been conditionally registered by the EPA-BPPD in 1996 as published in the EPA Reg. No. 524-492.[206] [207] The EPA generally defines risk as "unreasonable adverse effects on the environment" and recognises two regulatory implications of this definition, being first the need to assess the product's risk in the context of an analysis of possible "risks and benefits" and second, that pesticide residues and their effect on all dietary exposures must also be in conformity with the FFDCA tolerance and exemption provisions to be considered as "safe".[208] [209]

In assessing the active pesticide ingredients in MON810 in 1996 the EPA looked at product features and obliged Monsanto to elaborate on the term "use patterns".[210] [211] The hazard assessment addressed broader areas, namely the impact on the environment

202 Ibid., p. 32.

203 Ibid.

204 Ibid., p.1.

205 APHIS Draft Combined Documents: Notices Federal Register Vol.61:52, Friday, March 15 1996.

206 EPA Biopesticide Fact Sheet- Bacillus thuringiensis Cry1Ab Delta-Endotoxin and the Genetic Material Necessary for Its Production in Corn [MON 810] (006430) Issued: 4/00, p.1.

207 EPA Memorandum 1996.

208 The White House Case Study No. II: Bt-MAIZE, p.5.

209 FIFRA. (2008). Federal Insecticide and Rodenticide Act 2008. Article 2(bb).

210 The White House Case Study No. II: Bt-MAIZE, p. 15.

211 EPA Biopesticide Fact Sheet- Bacillus thuringiensis Cry1Ab Delta-Endotoxin and the Genetic Material Necessary for Its Production in Corn [MON 810] (006430) Issued: 4/00, p.1.

and human health.[212] Furthermore, the EPA focused on bacterial characteristics and toxic features in order to determine their level of equivalence with conventional products and concluded that Bt-maize protein was equivalent to those in other plant products.[213] As no hazardous or "acute oral toxicity" of the protein could be determined, MON810 was al owed for testing based on the EPA statement that "[t]here is a reasonable certainty that no harm will result from aggregate exposure".[214] The emphasis on 'unreasonable' adverse effects and a 'reasonable' level of certainty indicates that EPA considers both the risks and benefits of the pesticide and takes a decision subject to EPA safety standards, even in cases where uncertainty is present and risk- concerns remain unresolved.

Given that MON810 met the requirements under Title 40 of Part 180.1173 CFR it was conditionally registered and exempted "from the requirement of a tolerance".[215] The decision to grant exemption was based on the EPA's assumption that MON810 was 'safe' as defined in the FFDCA.[216] Nevertheless, the EPA had imposed restrictions on the use of MON810 and had limited the time of registration to five years. MON810 was conditionally approved because the EPA found in its risk assessment from 1996 that pest insects could possibly develop resistance to Cryl1Ab, but it reasoned that limitations on the use of the product would suffice to contain unwanted effects.[217] [218] Once more, this action shows the application of precaution in the case of uncertainty in order to counteract potential harm, however without restricting or banning the pesticide completely. The conditions imposed by the EPA entailed measures to limit the volume of MON810 cultivated in "certain regions of the country", the obligatory planting of "appropriately sized refuge of non-Bt-maize" and "post-approval monitoring".[219]

The conditional approval, still showing signs of precaution, was based on experience of using traditional breeding methods for conventional crops for GMOs.[220] As the National

212 Ibid., p.16.

213 EPA/ BPPD. Memorandum 1995 from Cough J to Mendelsohn M. Review of Product and mammalian Toxicology.

214 EPA Biopesticide Fact Sheet- Bacillus thuringiensis Cry1Ab Delta-Endotoxin and the Genetic Material Necessary for Its Production in Corn [MON 810] (006430) Issued: 4/00, p.2.

215 The White House Case Study No. II: Bt-MAIZE, p.23.

216 Ibid., p.5.

217 Ibid., p.20.

218 EPA Biopesticide Fact Sheet- Bacillus thuringiensis Cry1Ab Delta-Endotoxin and the Genetic Material Necessary for Its Production in Corn [MON 810] (006430) Issued: 4/00, p.15.

219 Ibid., p.23.

220 Tiedje *et al* 1986, p. 306.

Risk Council (NRC) pointed out this historical experience provides sufficient information to decide whether a product is safe or not.[221] The receipt of an application for the issuing of an Experimental Use Permit (EUP) and registration was published and made available for comments from the public.[222] In a final step, the FDA was also requested to voice its opinion with regard to "unintended effects, nutritional deficits etc." and other unresolved issues.[223] Based on its assessment the FDA responded by stating that no harmful or biological impact would follow from registering MON810 and thus no further consultations were needed.[224]

Overall, the introduction and approval process of MON810 took only five years and went relatively smoothly. Although situations of 'uncertainty' regarding possible risks emerged during this time, the competent US authorities were quick to react and to decide upon measures for the regulation of this uncertainty, such as the request for further information or the limited conditions for the planting of MON810. In contrast to EU agencies, which have merely advisory functions, the US bodies have formal decision-making powers. This seems to be an important factor for providing quick responses in situations of uncertainty.[225]

4.3 Pioneer 1507 in the EU

The case of Pioneer 1507 shows many similarities to the previously discussed case of MON810. In the EU, regulatory approval of TC 1507 as feed and approval as food was obtained in 2005 and 2006 respectively. This particular GMO was granted access to the EU market under Commission Decision (2006/197/EC)[226] and was based on the opinion issued by EFSA.[227] With reference to the working definition of this paper, EFSA's opinion -as the result of a risk assessment- might be considered an expression of precaution, as further

221 NRC. National Risk Council. Field Testing of Genetically Modified Organisms: Framework for Decision. Washington, D.C. National Academy Press 1989, p.16.

222 EPA. Pesticides: Regulating Pesticides. Bacillus thuringiensis Cry3Bb1 Protein Federal Register Notices 2005.

223 Freese & Schubert 2004, p. 311.

224 The White House Case Study No. II: Bt-MAIZE, p.12.

225 Parker & Alemanno 2014, p.27.

226 Commission Decision 2006/197/EC, 3March 2006 authorising the placing on the market of food containing, consisting of, or produced from genetically modified maize line 1507 (DAS-Ø15Ø7-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

227 Opinion of the Scientific Panel on Genetically Modified Organisms (reference EFSA-GMONL-2004-02), *The EFSA Journal* (2005) 182, 1-22. Retrieved from http://cera-gmc.org/docs/decdocs/06-066-001.pdf, last visited 20 May 2014.

information was required before a decision was taken. The EFSA report analysed the chemical composition of Pioneer 1507, looked information regarding the molecular inserts within the transgenic event, the questionable safety of the proteins in question and at the possible risks incurred when making a change to the chemical properties of Pioneer 1507. However, this extensive analysis resulted in the finding that, according to EFSA, there was no information or data that could lead to believe that Pioneer 1507 would be less safe than other non-genetically modified organisms on the food and feed market.[228] This report came to the same conclusion with regards to risks of environmental damage, be it for the possible increase in resistance to Bt toxin over the following years.[229] In relation to this potential hazard, the EFSA panel responsible for GMOs accepted the general surveillance plan that was handed in with the authorisation proposal for Pioneer 1507. Finally, the report concluded that, given the lack of evidence to prove otherwise, TC 1507 is not likely to result in bad effects on health or the environment. It therefore recommended that no restrictions or conditions be imposed on TC 1507, since the GMO panel did not deem them necessary.[230] This unsurprisingly resulted in the authorisation of TC 1507.

We may therefore conclude that first precaution was applied as in the MON810 case, since it can be identified to some extent in the ordinary risk assessment procedures by EFSA in addition to the national assessments. However, it remains questionable how precautious or inclusive of human health concerns the final decision of the Council actually was. After all, TC 1507 was permitted despite some concerns regarding increased resistance to Bt toxin. Therefore, as far as it was applied in the present case, the precautionary principle as defined in the working definition was not applied. Member States agreed on the authorisation of TC 1507 despite persisting concerns. In contrast to the MS resistance in the MON810 case, for the food and feed authorisation of TC 1507, MS seemed to be satisfied with the EFSA opinion and did not invoke the precautionary principle. The lack of any MS bans or considerable uproar in the TC 1507 case for food and feed may be explained by the fact that authorisation for food and feed is a lot less sensitive than that for cultivation, as was the case for MON810. On this level, we may therefore tentatively conclude that the overall regulatory approach taken by the EU was not overly risk averse as it is often voiced in academic discourse and that it may not have been as widely opposed from the US stance in this particular case.

228 Opinion of the Scientific Panel on Genetically Modified Organisms (reference EFSA-GMO-NL-2004-02). The EFSA Journal (2005) 182, p.21. Retrieved from http://www.efsa.eu.int, last visited 20 May 2014.

229 Opinion of the Scientific Panel on Genetically Modified Organisms (reference EFSA-GMO-NL-2004-02). *The EFSA Journal* (2005) 182, p.21. Retrieved from http://www.efsa.eu.int, last visited 20 May 2014.

230 Ibid.

However, large differences appear when briefly considering the ongoing debate concerning the authorisation of TC 1507 for cultivation. While the Pioneer 1507 case did not arouse a lot of controversy at the Member State level with regards to its authorisation for food and feed, the application for the GM crop to be authorised for cultivation sparked persisting disagreement and brought forward existing intra- EU differences in how one should proceed with the request: an issue that has not been resolved at this point.[231] The founder of the GM maize, the US American company Pioneer Hi-Bred International Inc., applied for such a cultivation authorisation within the EU in July 2001.[232] Interestingly, Pioneer Hi-Bred had deliberately notified Spain of its authorisation request, the EU Member State with the most far-reaching experience and established practice of growing and cultivating GMOs.[233] The *Comisión Nacional de Bioseguridad* (CNB), the respective Spanish authority, consequently assessed the case scientifically and concluded that "there is no reason to believe that imports, production, processing and cultivation of 1507 maize line, resistant to lepidopterae and tolerant to glufosinate, will have any negative effects on human health or the environment".[234] In the final conclusion of the seven-page assessment report the CBN however further and more specifically stated: the CBN "estimates that, for the considered uses, with the current level of knowledge, there is no scientific evidence to indicate that marketing of genetically modified 1507 maize line poses any risk".[235] Although the evasive and conditional answer – "considered uses, [...] current level of knowledge, [...]no scientific evidence to indicate[...]"[236]- clearly implies a certain level of uncertainty involved, the Spanish authorities decided to declare TC 1507 as not risky for cultivation. It remains questionable whether this was actually due to Spain's conviction that sufficient precaution had been applied through the risk assessment or whether other underlying motives were the cause for declaring TC 1507 cultivation acceptable. As mentioned previously, Spain's longstanding involvement in GMO growth

231 Delvaux 08-11-2013

232 Pioneer Hi-Bred & Mycogen Seeds, Document C/ES/01/01. *Summary Notification Information For Products Containing Genetically Modified Higher Plants (GMHPs) In Accordance With Directive 2001/18/EC*, 2001. Retrieved from http://www.gmo-compass.org/eng/gmo/db/75.docu.html, last visited 29 April 2014.

233 GMO Compass 23-03-2007.

234 Ministerio de Medio Ambiente. (n.d.) Assessment Report; Notification Number C/ES/01/01 to Market Genetically Modificed Maize (Line 1507) Resistant to Lepidopterae and Tolerant to Glufosinate -Ammonium Herbicide Submitted by the Company Pioneer, In Accordance with Directive 2001/18/EC, p. 1.

235 Ibid., p. 7.

236 Ibid.

and cultivation and thus economic interest could have played a role in its ultimate positive opinion about the pending application for cultivation. [237]

With the positive opinion from the Spanish authorities, the case was nonetheless far from being accepted and closed. While field trials of the GM crop were undertaken in various rather lenient EU Member States (Bulgaria, France, Italy: 2000; Spain: 2002[238]), mistrust against cultivation of the maize prevailed and a number of Member States remained concerned about issues such as the impact on human health, the environment and unintended consequences due to the genetic modification.[239] Notwithstanding the actual motivation behind this scepticism-possibly economic or political reasons rather than concerns about precaution-this demonstrates that there was not only diverging attitude towards TC 1507 and related risks between the US and the EU, but also within the EU, where some Member States recognised the possible cultivation of TC 1507 as an uncertain risk and others found it an acceptable risk. Nevertheless, as a significant number of Member States were not satisfied with the Spanish risk assessment report and unresolved questions remained, the European Commission ordered EFSA to conduct another risk assessment.[240] Despite intra-EU controversy over recognising uncertainty related to TC 1507 cultivation, the response by the EU to seek more assessments could be seen as an act of precaution. Regardless of the reasoning it certainly pinpoints EU-domination by the more precautious MS.

Following the request from the Commission, the GMO Panel of EFSA then adopted a scientific opinion on TC 1507 in January 2005 and concluded the GM maize to be as safe as conventional crops, just as in the MON810 case.[241] However, significant MS resistance persisted since MS found EFSA to have failed to fully satisfy the mandate previously received from the Commission. Notwithstanding the details of MS objections and questions, the Commission thus requested further review and clarification from EFSA which consequently added a clarifying annex to its opinion. The annex however mostly reiterated previous findings and finally stated again that "[...TC] 1507[...is] unlikely to have adverse effects on human and animal health or the environment in the context of [its...] proposed uses".[242]

237 GMO Compass 23-03-2007

238 EFSA Opinion of the Scientific Panel. The EFSA Journal, Issue 124, pp. 1-33. p. 9.

239 Ibid., pp. 1-3.

240 Ibid.

241 Ibid., pp. 25-26.

242 EFSA Scientific Opinion *The EFSA Journal,* Issue 851, pp. 1-27.

As Member States remained split over the risks of TC 1507 cultivation, they turned to EFSA once more for a revised second opinion. EFSA was however unable to provide significant new or more certain insights and thus issued a largely unchanged second opinion in October 2008.[243] The EU was only pressed for action on the application when Pioneer Hi-Bred brought an action for failure to act before the European General Court in 2007.[244] The case was however dismissed in 2009 due to ongoing Commission action and clear procedural steps to vote on a draft proposal for the authorisation of TC 1507 cultivation.[245] [246] There was nonetheless still no consensus and not even enough conviction to decide on the authorisation to reach qualified majority. The draft was consequently not adopted. What followed were renewed requests to EFSA to further investigate the effects and risks of a cultivation of the GM maize.[247] As the same MS remained sceptical and neither uncertainty nor reservations could be reduced, the Commission halted drafting procedures at its own level and referred the case to the ministerial level of the Council of Ministers.[248]

Despite increased pressure from Pioneer Hi-Bred which opted for a second action for failure to act before the EGC in 2010,[249] it took the Commission and the Council another three years to make a new attempt to react to the application. The EGC ruled in September 2013 respectively that "[...]the Commission must be considered as having failed to act"[250] and clearly "has failed to fulfil its obligations".[251] Following this judgement, the Commission finally put forward a second draft proposal in November of the same year that however closely resembled the first one.[252] It came as no surprise that the document, once put to a

243 Ibid.

244 Case T-139/07, *Pioneer Hi-Bred International v Commission* [2009] not published in the ECR.

245 Case T-164/10, *Pioneer Hi-Bred International v Commission* [2013] nyr., para. 10-13.

246 European Commission 'Draft Commission Decision of[...] concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a maize product (Zea mays L., line 1507) genetically modified for resistance to certain lepidopteran pests.' (Brussels, D003697/01).

247 GMO Compass 23-03-2007.

248 Ibid.

249 Case T-164/10, *Pioneer Hi-Bred International v Commission* [2013] nyr.

250 Ibid., para. 80.

251 Ibid., para. 81-82.

252 European Commission 'Proposal for a Council Decision concerning the placing on the market for cultivation, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a maize product (Zeamays L., line 1507) genetically modified for resistance to certain lepidopteran pests.' 2013). (Brussels, 06.11.2013 COM).

vote in the Council in early 2014, was rejected as well.[253] Despite claims by the Commission that Pioneer 1507 cultivation would actually have a majority of MS in favour and only a blocking minority,[254] 19 MS voted against the draft authorisation in February of this year.[255] Interestingly, the Commission had previously also sent a proposal to the Council to initiate a discussion about "[...]grant[ing] Member States more subsidiarity on [GMO] cultivation".[256] This development would of course be counteractive to a uniform EU regulatory approach towards GMOs and risk management as such. The question is, however, whether this would be such a bad thing after all. Given the tremendous procedural hurdles in the EU regulation process of controversial GMOs, it might even be a possible solution to make GMO regulation more effective. Such an improvement in speed and efficiency would certainly be in the interest of American GMO producers and related enterprises.

To conclude and highlight the relevance of the TC 1507 case for this study, it can be stated that the case, with regards to the pending application for cultivation authorisation (which has now been pending for more than a decade), neatly illustrates the intra-EU struggle for regulatory coherence. In light of the uncertainty related to possible effects of a TC 1507 cultivation, MS have been and are still split. They differ first, in the recognition of the degree of uncertainty and its implications, and second, in the preferred response to the uncertain risk of the GM maize cultivation: namely an authorisation or a ban. The compromised EU response to the TC 1507 application therefore turned out to take into account the various MS requests for precaution. Accordingly, the Commission repeatedly asked EFSA for further clarification of its risk assessment (four times in total!), although EFSA could obviously merely give a relatively certain scientific opinion on the uncertain risks related to the cultivation. Interestingly, the EU seemed to apply less precaution than its MS, as it continued to prepare draft decisions to authorise TC 1507 for cultivation. However, these always failed in the voting procedure, as no qualified majority could be reached due to persisting concerns and precautious attitudes of MS. It however remains to be further investigated what the actual motivation behind the respective EU and MS attitudes was. Regardless of the remaining uncertain risks, EFSA and national authorities widely issued positive opinions. The reason for MS resistance thus does not necessarily have to be based on need for precaution and concerns about human health and environmental protection.

253 GMO Compass 23-03-2007.

254 European Commission 'MEMO: Questions and Answers on EU's policies on cultivation and imports of GMOs' (Brussels, 06.11.2013).

255 Pop 11-02-2014.

256 European Commission 'Commission asks Council to agree on its proposal to grant Member States more subsidiarity on cultivation' Press Release (Brussels, 06.11.2013).

It can be concluded that, to date, the strong concept of precaution in the EU and the related precautionary principle have considerably influenced EU action and made risk management more complex and time-consuming as different interpretations of uncertainty and risk are involved across multiple levels. Nonetheless the TC 1507 case furthermore shows the power that precaution and related principles hold in the EU and the difficulty of uniformly regulating GMOs at Union level. This paper therefore challenges the notion that EU-US regulatory convergence could be either a likely or a desirable TTIP outcome.

4.4 Pioneer 1507 in the US

Seeing that their product characteristics are similar, it comes as no surprise that a similar regulatory approach was taken for both MON810 crop and Pioneer 1507. The EPA, the USDA and the FDA were involved in assessing the suitability of the crop for the US market, with this paper focusing on the scientific assessments undertaken by the EPA and the USDA. First, the assessments of the USDA/APHIS will be examined. In the US, a new crop is deemed a regulated article under 7 CFR part 340 if 'the donor organism, recipient organism, vector or vector agent used in engineering the organism belongs to one of the taxa listed in the regulation and is also a plant pest, or if there is reason to believe that it is a plant pest'.[257] This was deemed the case for Pioneer 1507 (as 'noncoding DNA regulatory sequences were derived from plant pathogens').[258]

A petition for determination, as provided for under section 340.6 CFR, of non-regulated status was submitted to APHIS by the companies Mycogen Seeds c/o Dow AgroSciences LLC and Pioneer Hi- BreInternational, Inc.[259] In June 2001 the APHIS issued an 'Environmental Assessment and Finding of No Significant Impact'.[260] In this assessment, APHIS considered the impact of having an unrestricted cultivation of the crop. The potential impacts assessed where: 'potential plant pathogenic properties', 'impacts from

257 Plant Protection Act Title IV, Pub. L. 106-224, 114 Stat. 438, 7 U.S.C. 7701-7772.

258 APHIS: The Animal and Plant Health Inspection Service Approval of Mycogen Seeds c/o Dow AgroSciences LLC and Pioneer Hi-Bred International. Seeking a Determination of Non-regulated Status For *Bt* Cry1F Insect Resistant, Glufosinate Tolerant Corn Line 1507: Environmental Assessment and Finding of No Significant Impact (June 2001), page 5.

259 Petition for determination of non-regulated status: B.t. Cry1F insect-resistant, glufosinate-tolerant maize line 1507 (10 May 2000).

260 APHIS: The Animal and Plant Health Inspection Service Approval of Mycogen Seeds c/o Dow AgroSciences LLC and Pioneer Hi-Bred International. Seeking a Determination of Non-regulated Status For *Bt* Cry1F Insect Resistant, Glufosinate Tolerant Corn Line 1507: Environmental Assessment and Finding of No Significant Impact (June 2001).

relative weediness of line 1507 corn compared to currently cultivated corn varieties', 'impacts from gene introgression from line 1507 corn into its sexually compatible relatives', 'impact on nontarget organisms', 'impacts on biodiversity', 'impacts on agricultural and cultivation practices', and 'impacts on raw or processed agricultural commodities'. In all of these aspects, APHIS found no difference, except for the characteristics of the crop intended, which distinguished Pioneer 1507 from a regular corn crop.[261] As a result, the conclusion was reached that 'after a review of the available evidence (...) APHIS believes that corn line 1507 wil be just as safe to grow as corn varieties that are traditionally bred or that have been deregulated under 7 CFR Part 340'.[262] Consequently, Pioneer 1507 was removed as a regulated article under the APHIS regulations 7 CFR Part 340.[263]

Looking at the arguments presented by USDA there is an apparent reluctance to recognise uncertain risks. The absence of evidence of an adverse effect seems to be fully sufficient for the agency. The case shows that what is recognised as uncertain risk is very limited. The agency is looking for evidence of a harmful impact. Uncertainty, on the other hand, does not seem to be a ground for keeping the product regulated under the CFR.

The paper now turns to the assessment undertake by the Environmental Protection Agency. The EPA has jurisdiction, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to regulate new substances in plants that are pesticides.[264] This means that the EPA does not regulate the new crop itself, but only one substance that this plant produces.[265] Concerning the Pioneer 1507 corn line, the EPA assessed the protein Cry1F that has been produced by means of genetically modification and that is responsible for developing the insect-tolerant characteristics of Pioneer 1507.[266]

As part of the scientific assessment of the protein, the EPA made both a human health, as well as an environmental assessment. For the former point, the EPA was satisfied with the data available and concluded that it was 'reasonable certainty that no harm wil result from aggregate exposure to the US population, including infants and children'.[267] Concerning the latter, it was satisfied with most data.

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261 Ibid.

262 Ibid.

263 EPA 40 CFR. US Federal Register 66 (139).

264 EPA Regulation of Biotechnology for Use in Pest Management

265 Ibid.

266 U.S. Environmental Protection Agency Biopesticide Registration Action Document: Bacillus thuringiensis Cry1F Corn (August 2001).

267 Ibid. page 13.

However, certain gaps and areas were identified in which more investigations were necessary (such as longer soil degradation study in actual field soil, more data as to the Monarch butterfly data and the continuation of beneficial insect field monitoring).

The EPA concluded that it was in the public interest that the Cry1F protein should be opened for production.[268] They based this view on their finding that the protein was 'less risky to health or the environment than currently registered pesticides'.[269] Additionally, the introduction had economic benefits.[270] However, because of the gaps in data in the environmental assessment only a conditional registration was allowed. An unconditional registration under FIFRA 3(c)(5) was not accepted. This shows that although the US might be generally quite lenient in accepting a certain amount of uncertainty, there is still a limit as to how much uncertainty is tolerated when introducing a GMO crop. By demanding more data in fields already investigated and new investigations in other fields, the EPA here shows that it does indeed act in a precautionary manner.

4.5 EU-US GMO Regulation: Putting the Findings in Context

Two main conclusions for the regulatory approaches of the EU and the US can be deduced from the case study analyses. First, with regards to the EU regulatory system there are considerable differences between the use of precaution at the EU level and the MS level. This was illustrated in the MON810 case, where both the EU and MS started from an equally precaution level, but the EU ultimately responded differently and less hesitantly to the uncertain risk surrounding the GMO. The EU demonstrated a precautious attitude toward the GMO by the simple action of asking EFSA to carry out an assessment concerning whether there was any reason to believe that the placing on the market of MON810 was likely to cause any adverse effects on human health and environment. Despite the remaining levels of uncertainty the Commission then relied on EFSA's positive scientific opinion and decided to place MON810 on the market. Against it, the number of MS that banned the cultivation of MON810 clearly relied on the precautionary principle by invoking the safeguard clause. However, the use of the precautionary principle in this case can possibly be attributed to other factors than purely scientific ones indicating that the scientific risk assessment cannot be assumed to be isolated from politically informed information. Political factors clearly play a role at the MS level. It therefore is often hard to determine whether or when the precautionary principle serves not only to protect

268 Ibid. page 40.

269 Ibid.

270 Ibid.

human health and the environment but is used as a political tool to protect the local economy or the like. This degree of politicisation is significant, as it could constitute a significant obstacle to both intra-EU risk governance coherence and convergence with US risk governance as in the negotiations on the TTIP.

The tensions between the EU and its MS have further been illustrated by the Pioneer 1507 case. While the case of TC 1507 for food and feed led to very similar EU and MS (and US) reactions, namely very little precaution, the authorisation request for cultivation highlighted larger differences. Regarding the cultivation of TC 1507, it is worth noting that although the US and EU approaches remained similar in their minimal application of precaution, there was a clear intra-EU tension between Member States. In light of uncertainty as shown in the EFSA assessments and vis-à-vis the lenient and loosely precautious stand by the US and the Commission, MS were largely reluctant to facilitate regulatory coherence and actively prevented a common EU response. Here again it was the MS that wanted to apply the precautionary principle in a stronger sense, possibly not exclusively for human health and food safety related reasons. Consequently, the EU approval process has taken more than a decade up to date and is not yet finished: an issue that indicates general EU problems in the timely implementation of its authorisation system. Regulatory coherence and politicisation of precaution, and therefore the limits to the idea of science-based risk management, thus constitute core issues to be taken into account when discussing EU-US regulatory convergence.

A second relevant finding is the remarkably more lenient stand of the US in applying precaution in light of uncertain risk. While both the EU and the US conduct risk assessment, the US is much quicker to act and often authorise a product by imposing restrictions in view of uncertainty. The regulation of MON810 in the US exemplifies that the regulation of products is based on a complex framework characterised by first, an application of existing laws regulating agricultural breeding and second, the interplay of different agencies that conduct risk assessment and take the decision on the safety of the product. Each product is analysed on a case-by-case basis and assessed by reviewing the scientific information. The US has measures in place that relate to 'precaution', but -based on the view of their main regulatory agencies- potential risk and uncertainty can be contained if certain conditions are imposed, such as monitoring, risk screening, limitations in registration time and volume. Also, a cost-benefit-analysis is conducted related to the scientific information available (and whether it is sufficiently clear and significant), and by taking into account experience with and records of similar genetically engineered organisms in order to make a safety assessment and a judgment on the release into the environment. The rather quick and determined decision-making and authorisation process concerning the release

of GMOs in the US stands in stark contrast to the long process and procedural obstacles in the EU, where decisions are often delayed by MS opposition. This is a significant finding and a problematic issue if even the slightest degree of regulatory convergence is to be reached between the EU and the US.

5. To Be or Not To Be: the TTIP

The Transatlantic Trade and Investment Partnership (TTIP) that is presently being negotiated between the EU and the US aims essentially at removing barriers to free trade. In this context, regulatory compatibility is one of the core issues in the ongoing negotiations. Negotiators now need to discuss how to solve differences in their diverging regulatory systems on goods amongst others. Through its case studies, this paper has tried to draw conclusions as to possible areas of controversy, such as the diverging notions on precaution, systemic disparities and the prospect of regulatory convergence and whether this would present a desirable scenario after all. Several problematic issues are still on the TTIP negotiation table and still need to be dealt with. These include differences in food safety standards and the two-decades-old GMO dispute. previously mentioned, the dispute between these two economic giants has evolved due to divergence in the so-called "sanitary and phytosanitary (SPS)" rules, including hormone-treated beef, raw-milk cheese and chlorine-washed chicken.[271] In this regards, the TTIP is different from other free trade agreements that mainly deal with traditional trade issues such as tariffs, as it will instead focus on the removal of so-called 'nontariff barriers'.[272] These nontariff barriers are essentially the regulatory differences between the EU and the US that can be seen in diverging regulations and requirements concerning food safety, environmental, chemical and consumer standards amongst others.

As diverse food safety standards have led to a trade dispute between the US and the EU for many years now, and in light of the relevant differing risk governance approaches, the protracted conclusion of the TTIP talks has already highlighted the difficulties in agreeing on a common denominator. The EU/US differences in regulation have possibly evolved due to a lack of common understanding regarding what constitutes 'risk' and how it should be assessed and governed. Supposed concerns regarding consumer protection legitimise

271 *Ibid.*

272 Lester, Barbee, 2013, p. 848.

varying standards of risk management and equally allow for the politicisation of risks.[273] This paper highlighted the main differences and incompatibilities in the debate on GMOs.

At the core of the differences in regulatory approaches stands therefore the notion of precaution as a justification for regulatory measures. In the case of the EU, the frequent application of the precautionary principle constitutes a strong expression of a stricter regulatory system than that of to the US. This is especially illustrated by the EU Member State practice of invoking the safeguard clause or applying emergency and precautionary measures contained in the GMO regulations and the related EU legal framework. After having a closer look at the aforementioned case studies, this paper may confirm the overspread view that Europe is "more precautionary" than the United States. Although the US also reflects the precautionary principle, it appears in a highly "compromised form".[274] Nevertheless, such a claim must further be assessed with regards to the actual motivation behind stricter regulation of GMOs within the EU, given that the cases indicate that other reasons may be the cause for invoking the precautionary principle, such as protection of the national economy or bidding for domestic votes. Precaution as identified and understood in the working definition of this paper has therefore been taken more frequently and extensively by the EU than the US, but it remains to be investigated whether regulatory measures at the EU level always really are about precaution and concerns regarding the environment, human and animal health.

Nonetheless, the differences found in the case studies imply that it will indeed not be an easy task for the EU and the US to agree on a common denominator in the TTIP negotiations, and that it will certainly not be possible without concessions. Drawing on the previously outlined conclusions of the cases, there are a number of significant differences in the respective regulatory approaches that this paper would like to point out and bring to the attention of the TTIP negotiators. Although both the EU and the US seem to have a similar recognition of uncertainty and uncertain risk in the earlier stages -as positive EFSA and APHIS/EPA opinions and analogical risk assessments illustrate- their responses to uncertainty vary considerably. It can therefore be stated that the legal and procedural frameworks requiring initial risk assessment may well be rather compatible at first sight. However, difficulties ultimately arose in the political decision-making and the implementation stage in the analysed cases. When taking a closer look at the risk

273 European Commission, "Questions and answers" in In focus: Transatlantic Trade and Investment Partnership (TTIP). Retrieved from http://ec.europa.eu/trade/policy/in-focus/ttip/questions-and-answers/, last visited on the 27th of May 2014.

274 Applegate, 2000, p. 415.

management levels of the analysed cases, it became evident that the EU level resembled the US regulatory approach so far as it took a more lenient approach vis-à-vis uncertain risk. The Commission usually follows EFSA's positive opinion on the authorisation of the concerned GM product, while declaring remaining uncertain risks as acceptable. Authorisation is then usually hindered or blocked at the Member State level. This can be seen on various occasions in the analysed cases, for instance in the Council of Ministers. Even if the Commission were to lobby towards the authorisation of a GMO, no regulation can be passed for EU-wide application without a qualified majority at the ministerial level. Likewise, even after an authorisation has been passed in the Council, Member States are able to undermine the implementation by invoking the safeguard clause.

In this context, it is consequently striking that compatibility problems mostly originate from the MS regulatory approaches, while the Commission seems to take a more or less similar stand to that of the US. Despite an overarching EU regulatory system for GMOs, inner EU regulatory coherence- difficulties arise from disparities in the implementation phase. This may therefore constitute an essential issue on the TTIP negotiation table with regards to the successful combination of free trade and risk governance and is furthermore relevant in light of economic ties, since US American companies have a strong interest in expanding into the European market. These procedural shortcomings that are closely linked to the EU-MS friction regarding GMO regulation must therefore be dealt with. As long as it is possible for applications to remain pending for more than ten years -as is the situation in the Pioneer case- or products may finally be authorised on the EU level but then banned by various MS, transatlantic trade will be significantly hindered. This ultimately means that the EU regulatory framework that provides MS with the power to block GMOs must be re-discussed. This entails that timely approval (or ban) of GMOs by the EU could be a core issue in the TTIP negotiations, although it is mostly an EU problem.

While the importance of the preservation of food safety standards cannot be neglected, it should nonetheless and especially be in the interest of European policymakers to adapt or improve intra-EU regulatory decision-making in order not to alienate US companies and other important market actors from the European market. The recent withdrawal of the application for GMO authorisation by Monsanto points towards a beginning of such a resignation by firms that are frustrated with the European regulatory framework.[275]

Looking now at the issue from the other side, there are also a number of issues on the part

275 Hope, 'Major GM food company Monsanto 'pulls out of Europe'. *The Telegraph* (2013). Retrieved from http://www.telegraph.co.uk/earth/environment/10186932/Major-GM-food-company-Monsanto-pulls-out-of- Europe.html, last visited 12 June 2014.

of the US that could be problematic when striving to agreeing on common denominators in the TTIP negotiations. One of them has been highlighted by the case studies, namely the multitude of different actors and agencies involved in the steps leading to a GMO regulation or authorisation, often with conflicting assessments. Complexity reduction could therefore be a topic of reciprocal efforts in the TTIP negotiations: one in which both parties could learn a lot from each other and considerably improve the effectiveness of their systems. Nonetheless, the issues of intra-EU discrepancy in the implementation of regulations and the abundance of risk-assessing agencies and influential actors in US regulatory processes may very well be problems that must be resolved by the EU and the US separately.[276] The case studies have demonstrated the complexities of the GMO debate and the varying regulatory systems. They have further shown that MS involvement on the regulatory level in the EU may not always be about precaution as such and thus this paper questions the validity of the claim that regulatory convergence is a precondition for the successful conclusion of the TTIP.

If anything approaching convergence were to be reached, concessions would have to be made on both sides. Given the higher complexity and rigorousness of the regulatory framework in the EU, it could however pose a delicate and difficult problem to agree on an approximation of standards with equal concessions, especially in light of the tremendous differences in safety standards. EU regulations for instance currently prohibit the use of 1,300 chemicals in cosmetics, while US regulations only ban 11 substances from being applied in cosmetics.[277] Regardless of the outcome of the TTIP negotiations, if regulatory convergence is the aim, significant sacrifices of precaution would most likely have to be made on the part of the EU. It has been argued that the pursuit of global regulatory convergence can result in either "the race to the bottom" of weakening protective standards or in "the race to the top" of improving such standards.[278] Consequently, converged standards would be likely to approximate to the advantage of the US.[279] This could of course make it rather difficult to come to an agreement in the first place. Additionally, even if regulatory convergence were achieved in this manner, this would not necessarily resolve the implementation problems and resistance of EU MS. This may therefore be yet another argument for working around the differences rather than towards convergence at the sacrifice of precaution standards.

276 Further research needs to be conducted.

277 Strasser, 'Es war einmal ... die schönsten Märchen über TTIP'. *Blog.campact!* (2014). Retrieved from http://blog.campact.de/2014/05/es-war-einmal-de-guchts-schoenste-ttip-maerchen/, last visited 12 June 2014.

278 Vogel, 2012, p. 280-282.

279 *Ibid.*.

Policymakers should therefore make their redlines known up front and be highly aware that whatever is finally concluded will have an immediate impact on both European and US consumers who are following the ongoing TTIP talks with differing concerns. The negotiators should consequently engage in an open dialogue on systemic differences and the disparities in consumer protection and food safety cultures. Addressing regulatory differences is particularly important in order to ensure a more informed public debate which has become increasingly polarised mainly due to the dissatisfaction with the level of transparency.[280] These immediate conclusions from the case studies have highlighted a number of controversial points with regards to the ongoing TTIP negotiations and the debate over how best to achieve the removal of barriers. While the findings of this study have shown that regulatory convergence may not be the best way to go about this, since it may rather result in significant sacrifices of precaution on part of the EU, it may also be rather difficult to achieve convergence due to persisting complexities of the different systems, as highlighted above. In addition, there are alternative scenarios to deal with regulatory differences between the EU and the US that are more likely to happen.

5.1 The Involvement of Stakeholders and Investor-State Arbitration

The TTIP negotiations are accompanied by stakeholder consultation events during which EU and US stakeholders are given the opportunity to present their views on various aspects of the TTIP to the negotiators and other participants.[281] The events are frequented by a wide array of stakeholders such as representatives from the industry, small businesses, labour unions and environmental groups to name just a few.[282] Despite being an opportunity for negotiators to receive feedback on the ongoing talks, stakeholder comments must be taken seriously as they represent among others the voices of the world's largest agribusinesses, thus voicing their underlying economic interests. One of the most important stakeholders, in the context of this paper, is the Biotechnology Industry Organisation (BIO).[283] BIO represents the bulk of the biotech industry, including

280 Alemanno, "A reality check of TTIP: beyond the popular account". *EurActive,* 2014.

281 European Commission TTIP– Stakeholder event in Brussels. Retrieved from http://trade.ec.europa.eu/doclib/press/index.cfm?id=1027, last visited 2 June 2014.

282 Office of the United States Trade Representative (2013) Stakeholder Engagement Events. Retrieved from: http://www.ustr.gov/about-us/press-office/blog/2013/December/TTIP-Third-Round-stakeholder-engagement, last visited 2 June 2014.

283 BIO is the largest trade organization to serve and represent the biotechnology industry in the US and worldwide. BIO (n.d.) Company Profile. Retrieved from http://www.biospace.com/company_profile.aspx?CompanyId=1311, last visited 2 June 2014.

GMO producers such as Monsanto, Pioneer Hi- Bred International and Bayer CropScience among many others.[284] Regarding transatlantic trade in agricultural commodities, BIO states that their primary concern is 'asynchronous approval' of GMOs in the EU and the US.[285] According to BIO, this asynchronous approval is caused by lack of alignment of risk assessment methods and non-scientific delays in product approvals.[286] Consequently, BIO would like to obtain a TTIP outcome that will ensure evidence-based risk assessment, consistent implementation of existing EU legislation in line with both US and international standards and timely approval.[287] [288]

As the company in the Pioneer case, BIO previously criticised the EU's failure to act and the zero- tolerance policy that make it increasingly difficult to import commodity grains from countries that widely use GM varieties. Accordingly, BIO demands the Commission to authorise all products that have received a positive scientific opinion by EFSA.[289] The incorporation of stakeholder demands like these would of course collide with the reservations of EU Member States, which could still ban GMOs at the national level. Although stakeholders and investors' voices are naturally important in the establishment of a transatlantic free trade zone, their interests do not have to erode existing EU legislation. To these ends, entrepreneurs have reiterated that "[...] from a company perspective [...] the [EU] legislative framework is actually fine – it's very workable.... It's the implementation of the legislative framework that poses the greatest chal enge".[290] Likewise, voices on the EU side of the Atlantic have stated that EU legislation does not need to be adapted, but instead the operation and effects of these regulations should be tackled in any proposal for the removal of barriers to free trade.[291]

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284 Biotechnology Industry Organization (n.d.) List of Members. Retrieved from http://www3.bio.org/BioMembers/members_view_all.aspx, last visited 2 June 2014.

285 BIO, Transatlantic Trade and Investment Partnership – Comments submitted by: Biotechnology Industry Organization (BIO) Docket Number: USTR-2013-0019. p.14. Retrieved from http://www.bio.org/sites/default/files/BIO%20TTIP%20submission%20May%202013%20fina l%205%2010%201 3.pdf, last visited 2 June 2014.

286 *Ibid.*

287 *Ibid.*

288 Biotechnology Industry Organisation (n.d.) EU-U.S. High Level Working Group on Jobs and Growth Response to Consultation by EuropaBio and BIO. pp.3-4. Retrieved 3 June 2014 from: http://ec.europa.eu/enterprise/policies/international/cooperating-governments/usa/jobs-growth/files/consultation/regulation/15-europabio-bio_en.pdf

289 *Ibid.* p.6.

290 'Biotech Advocates Seek to Alter Operation of EU GMO System, Not Law', 2013.

291 Pollack, Annual Meeting Paper; American Political Science Association, 2013, p. 33.

One way to work around existing legislative frameworks could possibly be an external dispute settlement mechanism. In this context investors have recently come to support the proposed investor- state dispute settlement (ISDS) mechanism of the TTIP negotiations. This mechanism would most likely follow the example of currently existing bilateral and multilateral investment protection agreements.[292] The purpose of such agreements is to grant investors certain rights in order to enable them to protect their (foreign) investments and ways to enforce these rights vis-à-vis national governments in international tribunals that have standards and regulations in place in order to limit or prohibit certain business activities if they undermine their environmental, health or safety standards.[293] [294] The ISDS therefore aims to finding a balance between the states' right to regulate and the need to protect investors.[295] However, the significance of the ISDS for the role of precaution in the context of the TTIP and the GMO debate must be critically assessed. It remains questionable to what extent investors should be empowered to interfere with the regulatory systems, particularly when it might involve sacrificing precaution for economic benefits.

In the past, there have already been attempts to solve the dispute surrounding the EU MS application of precaution and the precautionary principle, shown concretely in a number of complaints lodged with the WTO. Industry lobby groups and corporations attacked the application by qualifying it as unscientific and grounded more in politics than sound science, thereby exerting pressure on the negotiators.[296] As shown earlier in this paper, the disputes have been over the restriction of specific GMOs by the European Union, which were previously approved in the US. The EU's GMO authorisation rules have been found not to conform to the WTO rules. In addition to that, the safeguard measures and their application are deemed to be inconsistent with the WTO principles. It can be concluded that the WTO as a dispute resolution mechanism may currently be unable to solve the transatlantic trade dispute.

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292 Behn, The TTIP, Investor-State Dispute Settlement, and the Future of International Investment Law in the EU and Norway, 2014. Retrieved from http://blogg.uio.no/jus/smr/multirights/content/the-ttip-investor-state-dispute-settlement-and-the-future-of-international-investment-law-in , last visited 9 June 2014.

293 Webb, Treaty Shopping, Retrieved from http://infojustice.org/archives/28044, last visited 9 June 2014.

294 TACD; Resolution on Investor-State Dispute Resolution in the TTIP (DOC NO:TRADE 15/13). Retrieved from http://www.consumersinternational.org/media/1398522/tacd-ttip-resolution-on-investor-state-dispute- resolution.pdf, last visited 9 June 2014.

295 European Commission Fact sheet on Investment Protection and Investor-to-State Dispute Settlement in EU agreements, 2013. Retrieved from http://trade.ec.europa.eu/doclib/docs/2013/november/tradoc_151916.pdf, last visited 27 May 2014.

296 *Ibid.*

The proposed investor-state dispute settlement mechanism as one possible tool could be used to deal with working around the current stringent EU GMO regulations and the deadlock in the WTO. The dispute resolution panels or systems of the ISDS stand in stark contrast to WTO dispute settlement, as not only governments can bring claims forward, but also private investors.[297] Nevertheless, scholars argue that ISDS may be biased to the advantage of investors, since governments can merely defend themselves under this mechanism.[298]

One prominent example case in this regard is *Philip Morris Asia Limited v. The Commonwealth of Australia*.[299] The American-based tobacco producer Philip Morris International brought actions via its Asian subsidiary, Philipp Morris Asia Limited, against the government of Australia. In 2011, it attempted to challenge the Australian Tobacco Plain Packaging Act,[300] claiming damages for "indirect expropriation"[301] of profits it was unable to make due to this law.[302] Additionally, it sued the Australian government on the grounds that national law was infringing the company's intel ectual property rights, and claiming not only monetary compensation but also the removal of the restrictive regulations.[303] [304] As the case is still pending, it remains to be seen whether and to what extent Philip Morris international wil be able enforce its rights against Australia and thereby limit the Australian "sovereign prerogative to make regulatory changes in the public interest [..]"

297 *Ibid.*

298 Van Harten, 2013.

299 Case No. 2012-12 *Philip Morris Asia Limited v. The Commonwealth of Australia*.

300 Tobacco Plain Packaging Act 2011, Act No. 148, (Cth.) (Bill) (Austl.). Retrieved from http://www.comlaw.gov.au/Details/C2011A00148, last visited 11 June 2014.

301 TACD; Resolution on Investor-State Dispute Resolution in the TTIP (DOC NO:TRADE 15/13). Retrieved from http://www.consumersinternational.org/media/1398522/tacd-ttip-resolution-on-investor-state-dispute-resolution.pdf, last visited 9 June 2014.

302 Australian Government; Tobacco plain packaging-investor-state arbitration, 2014. Retrieved from http://www.ag.gov.au/internationalrelations/internationallaw/pages/tobaccoplainpackaging.aspx, last visited 9 June 2014.

303 Webb, 2012. Retrieved from http://infojustice.org/archives/2804, last visited 9 June 2014.

304 Taylor, Morris v Australia: the Challenges of Investor-State Arbitration, 2014. Retrieved from http://www.mallesons.com/publications/marketAlerts/2011/International-Arbitration-Update-November-2011/Pages/Philip-Morris-v-Australia-the-challenges-of-investor-state-arbitration.aspx, last visited 11 June 2014.

and preserve precaution.[305] [306] This case therefore possibly foreshadows a conflict between investors' and public interests.

If ISDS is included in the TTIP provisions, such a mechanism will be very likely to have implications for safety standards and for the regulation of GMOs. Other arbitration cases like *Vattenfall v. Germany (II)* and *Eli Lilly v. Canada* have demonstrated the leeway that investors have to find loopholes and provisions to challenge national laws.[307] [308] The exact wording and limitations of the TTIP provisions establishing a transatlantic EU-US ISDS will most likely determine whether consumer protection and regulatory standards will be effectively lowered in the name of free trade or whether those provisions are phrased with the aim of preserving precaution: namely to find a mid-way for ensuring the co-existence and the protection of foreign investment and public health, safety and the environment. In this regards, EU Commissioner Karel De Gucht has already pointed out that ISDS in a rewritten or new form will follow this mid-way direction and that limits on the arbitration will be set up.[309] To these ends, experts recommend that a TTIP dispute settlement should be based on the rule of law and good regulatory practices.[310] [311]

To sum up, introducing an ISDS mechanism under the TTIP does not come without controversy, as it enables the investors to directly bring a claim of expected income loss against the authorities of the host country in front of an international tribunal.[312] This

305 Behn, The TTIP, Investor-State Dispute Settlement, and the Future of International Investment Law in the EU and Norway, 2014. Retrieved from http://blogg.uio.no/jus/smr/multirights/content/the-ttip-investor-state-dispute- settlement-and-the-future-of-international-investment-law-in , last visited 9 June 2014.

306 Morris International, BIT, Arbitration: Philip Morris Asia Limited & The Commonwealth of Australia. Retrieved from http://www.pmi.com/eng/media_center/company_statements/Pages/bilateral_investment_treaty.aspx#, last visited 11 June 2014.

307 *Vattenfall AB and others v. Federal Republic of Germany* , ICSID Case No. ARB/12/12.

308 *Eli Lilly and Company v. The Government of Canada* [2012], Notice of Intent to Submit a Claim to Arbitration under NAFTA (Nov. 7, 2012). Available at: http://italaw.com/sites/default/files/case-documents/italaw1172.pdf, last visited on 9 June 2014; See also: NO FRACKING WAY | How the EU-US trade deal risks expanding fracking in Europe and the US | news release [2014]. Retrieved from http://vimeo.com/88146142, last visited 27 May 2014.

309 Ermert, TTIP: EU Commissioner Points Finger At US Secrecy, Investor-State Provisions. Retrieved from http://www.ip-watch.org/2014/04/02/ttip-eu-commissioner-points-finger-at-us-secrecy-investor-state-provisions last visited 9 June 2014.

310 Alemanno, "A reality check of TTIP: beyond the popular account". *EurActive*, 2014.

311 Behn, The TTIP, Investor-State Dispute Settlement, and the Future of International Investment Law in the EU and Norway, 2014. Retrieved from http://blogg.uio.no/jus/smr/multirights/content/the-ttip-investor-state-dispute-settlement-and-the-future-of-international-investment-law-in, last visited 9 June 2014.

312 *Ibid.*

is feared to be a tool for the multinational corporations "to whittle away EU standards and regulations across a range of policies from the environment to food safety to social protection".[313] Negative examples of such practice are already starting to show, as for example in the previously mentioned cases. For Member States that wish to take a precautionary stance towards GMOs, such a mechanism might become a great financial burden and could further limit governments' ability to exert precaution vis-à-vis uncertainty. In this context, the current Commission proposal for an opt-out possibility for EU Member States regarding GMO cultivation appears to be contradictory, as MS could then be sued under ISDS for making use of this possibility.[314] Consequently, the intended expansion of MS sovereignty and control over GMOs could be turned against them through ISDS. The prospect of being sued under investor-state arbitration might further entail the danger of altering risk governance in the sense that national regulatory decision- making would be influenced by industry demands. In such a scenario, national GMO regulatory measures would no longer only be based on the assessment of uncertain risks, but would have to additionally take into account investors' concerns.

Notwithstanding the lack of details at the moment with regards to the final form of ISDS in the TTIP, this is an issue that cannot be disregarded given the fast growing number of ISDS cases in the last decade.[315] In light of the concerns regarding precaution and reiterated calls by the Biotech industry for strong investment provisions in the TTIP, it will be important to prevent a shift of risk governance away from uncertain risk and precaution towards economic interests and the satisfaction of stakeholders. If ISDS lead to a governmental focus on avoiding law suits, the protection of the environment, human and animal health would then find itself taking a back seat in regulating uncertain risk.

313 Quoted in "Brussels wants to hear more on TTIP investor-state dispute clause" http://www.euractiv.com/trade/brussels-wants-hear-ttip-investo-news-532919, last visited 27 May 2014.

314 GMO: Commission asks Council to agree on its proposal to grant Member States more subsidiarity on cultivation, European Commission, 2013.

315 Suing the State: hidden rules within the EU-US trade deal 2013.

6. Conclusion and Future Outlook

This paper investigated the differences between the EU and US regulatory systems with regards to the GMO debate. The international dimension of this debate has already demonstrated that there are significant disparities between the systems, as this paper highlighted in its revision of the WTO attempt to solve the EU-US dispute over GMOs. What can be concluded generally in this regards is first that it appears to be quite paradoxical how risk governance continues to rely on national responses vis-à-vis global risks. Second, these different responses seem to go back to persisting different understandings of what constitutes risk and how to deal with uncertainty. The comparative analysis of MON810 and Pioneer 1507 further confirmed the existence of considerable regulatory differences and more extensively evaluated the actual issues at stake. The cases illustrated the often-voiced trend of a more lenient US and a more risk-averse EU. However, they moreover illustrated that GMO regulation at the EU level, or rather at the level of the Commission, may not necessarily be as rigorous as it is often stated in academic discourse. Instead main differences to the US system mainly originated at the Member State level in the case studies. On that score, this paper found that MS opposition or support vis-à-vis GMOs might not necessarily be an expression of precaution or a deliberate acceptance of uncertain risk. Other motives such as the protection of national economies or the desire to remain competitive in the global GMO market may cause MS to adopt their respective positions toward precaution and particular GMOs. Different degrees of precaution must therefore be very critically questioned in the area of their underlying rationale.[316]

This paper further set out to draw conclusions from the cases for the impact of regulatory differences onto the TTIP negotiations. The transatlantic disparities regarding GMO regulation are indeed very relevant for the TTIP, as it is essentially a negotiation of a free trade zone between the EU and the US, while EU product authorisation depends on consent of the national MS. GMO regulation can therefore not be addressed at a mere EU-US level in the TTIP talks, but must include the MS, who can facilitate or hinder implementation of GMO legislation. This paper moreover touched upon the question whether regulatory convergence in a TTIP framework would be desirable and realistic. It concluded that convergence of risk governance systems would be highly difficult and very unlikely for a number of reasons that mainly include a prospective outcome to the disadvantage of the EU. First, an approximation of EU-US standards would probably result

316 Further research needs to be conducted.

in a lowering of EU standards and thus be a sacrifice of EU precaution. Second, a common EU-US regulatory framework would furthermore shift decision-making power away from EU MS and thus not be in their interest. Finally, EU policymakers have already repeatedly denied that any such changes will be made in EU legislation on GMOs and precaution.

While this paper discussed the possible meaning of regulatory disparities for the TTIP, it recognised that the TTIP is moreover essentially a trade agreement. Therefore, any outcome bears the risk of being focussed mostly on economic benefits and profits. The study of scenarios related to the involvement of stakeholders as well as the ISDS illustrated the danger of sacrificing precaution in the name of free trade. The case studies likewise demonstrated this difficulty of balancing industry interests and national levels of GMO regulation based on claims of precaution. Precaution, from an economic perspective, could thus be a means to justify scepticism about a GM product, although concerns may in reality be about suffering loss in the national market. As precaution may therefore be an argument frequently used for GMO regulation, especially by but not limited to EU MS, it may not necessarily be the actual motivation behind regulatory actions.

Overall, it can be said that EU and US regulators should be aware of the danger of losing sight of the role of precaution in the TTIP negotiation. The focus on economic aims may very well lead to claims about precaution that do not originate in concerns about the protection of the environment, human and animal health. Economic interests are certainly intermingled with regulatory decisions and precautionary measures in light of uncertain risks. TTIP negotiators may consequently find it helpful to separate these different goals carefully and work towards the successful conclusion of the TTIP in the name of free trade and precaution rather than sacrificing the latter in the process.

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