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MaRBLe Research Papers

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Introduction

Regulating Innovation, Trade and Uncertain Risks

Due to experiences such as the Chernobyl disaster, the asbestos tragedy, various food scandals and comparable experiences, in modern times technology-based innovation is often associated with risks that are highly uncertain. In other words, there are suspicions about potential hazards to human health or the environment for which there is no scientific proof, but which cannot be fully refuted either (Van Asselt & Vos 2006). Following scandals such as the BSE crisis where uncertain risks were initially ignored and governments and experts attempted to reassure the public with zero risk statements, the current societal climate in which innovation takes place can be characterized as 'post-trust' (Löfstedt 2005).

Technology-based innovation poses significant challenges to regulators. In the early stages of the innovation process, when technology could be controlled relatively easily, one does not know enough about harmful consequences to issue regulation, whilst at a later stage, by the time consequences are apparent, control by regulation is expensive and drastic. This dilemma is referred to as the Collingridge dilemma of control of technology (Collingridge 1980). Furthermore, research into health and environmental impacts usually lags behind: by the time first insights are available, the research is already outdated because new generations of the technologies are already available (Harremoës et al. 2002)

Regulators are foremost confronted with the obstacles to innovation in the context of trade: the free circulation of innovative products may be blocked by states or trade blocks for reasons of protection of human or environmental health. Controversies about innovation and uncertain risks therefore often have trade consequences. Many of the complex cases that challenge the EU or the World Trade Organisation (WTO) in their ambition for further market integration pertain to conflicts about innovation and uncertain risks (Prévost 2014). The question often is how to allow free trade while at the same time ensuring that the protection of human and environmental health is duly taken into consideration. Trade conflicts concerning genetically modified organisms (GMOs) and hormones in beef are iconic examples.

In such controversies, all parties involved focus on science to defend their case in their efforts to justify or challenge the trade barriers. So the role of scientific expertise in such conflicts is critical. Policy-makers and judicial authorities resort to experts for conclusive

evidence and definite answers, while scientific experts cannot provide certainty about uncertain risks. Often the risks are not even sufficiently understood to carry out a proper risk assessment, although legal provisions require that risk assessments are performed. Such regulatory complexities have been described as the uncertainty paradox: although uncertainty is acknowledged, the role of science is framed in terms of providing certainty, which framing seduces, forces or at least invites scientific experts to provide so-cal ed "plausibility proofs" about uncertain risks (Van Asselt & Vos 2006).

Questions regarding the regulation of trade and innovation increasingly boil down to questions of governance of uncertain risks. This question is firmly on the societal agenda, as policy advices of, among others, the Dutch Health Council (2008), the Scientific Council for Government Policy (WRR) (2008; 2011) and the UK Health and Safety Executive (HSE) and the existence of the International Risk Governance Council (IRGC) testify. Setting (new) rules of the game is an ethical, political and legal task, which requires a sophisticated understanding of current practices.

Over the past years, we have demonstrated that interdisciplinary law – social science research is needed to adequately understand current regulatory practices and the societal dynamics around innovation, trade and uncertain risks. Legal scholars (but also policy makers and judges) generally take the role of science and experts for granted and/or fail to comprehend the specifics of science which leads to overconfidence in science. Legal scholars usually focus on procedures and court cases, ignoring the societal context and the political dynamics that shape the cases. Social scientists (such as sociology, social studies of science and technology, risk research, political sciences, European studies, studies of culture / anthropology) examine societal and political processes and question the role of science and experts, but usually ignore or misrepresent the relevant legal frameworks and they have serious difficulties in reading and understanding law, procedures and court cases. Social sciences, furthermore, have a troublesome relationship with normative evaluations and policy recommendations, while that is core business in law. So joining forces is needed to be able to critically assess the role of science and expertise in trade controversies that involve innovation and uncertain risks and which are shaped by national, European Union and WTO legal frameworks (Van Asselt, Versluis & Vos 2013; Van Asselt, Everson & Vos 2014).

Research-based learning within the MaRBLe project

These challenges were therefore taken up in this MaRBLe project between the academic years 2010-2011 and 2013-2014. The project thus aimed at allowing students to participate in pioneering interdisciplinary research investigating the complex relationships between science, society, politics and law. It offered students a chance to make a positive contribution to the emerging interfaculty research program on risk, uncertainty, law and governance. A critical objective for students has been to build competences in these fields, as well as develop specific interdisciplinary skills. Through participation in this MaRBLe project, the students were thus enabled to better evaluate the prospects and the challenges of interdisciplinary research and develop a better understanding of the critical issues pertaining to innovation, trade and uncertain risks. Within the framework of the project, students have analysed controversies around innovation where the risk aspects of trade and the trade aspects of risk are at stake, with a particular focus on the regulation of GMOs. The students within this MaRBLe project have thus investigated current cases that involve innovation, trade and uncertain risks that have not been researched yet. The format that was adhered to in the course is the one of teamwork. We felt that, as interdisciplinary research requires the exchange of expertise and perspectives, this would be an excellent way to experience interdisciplinary research in practice.

By doing their specific research, the students have also been contributing to our ongoing research and to the development of our research agenda. As such, we therefore can say that we have benefitted from the students' research, confirming the course's truly research-based learning environment. Hence, one of the MaRBLe papers of this project written in 2011, was further developed in an academic paper, and was published in the peer-reviewed and renowned Journal of Risk Research (Drott et al., 2013).

Acknowledgements

This working paper publishes all papers written by students within the framework of this project between 2010 and 2014. It shows the diversity of topics studied and highlights difficulties with which regulators, in particular the EU are struggling in their attempt to come to grip with uncertain risks in relation to innovation and trade.

We would like to thank first all students for their dedication to the research and their hard work. We would also like to thank all teachers in this course who joined us in this event over the past years: Tessa Fox, Marijke Hermans, Frederic Bouder, Denise Prévost and Maria Weimer. We also would like to thank the external experts who with their knowledge and expertise enriched the research carried out and underlined the importance of this kind of interdisciplinary research, Ragnar Löfstedt (King's College, Centre for Risk Management), Ruth Mampuys (Netherlands Commission on Genetic Modification (COGEM)) and Annick de Vries (Rathenau institute).

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Marjolein M.B. van Asselt & Ellen Vos

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Academic Year 2010–2011

Accountability and Risk Governance:

A Scenario-informed Reflection on European Regulation of GMOs

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1. Uncertain Risks, Organized Irresponsibility and Accountability Problems

Scientific and technological progress in an ever more globalized economy has resulted in new innovations, which have often contributed to improved living conditions (Archibugi and Iammarino 1999; Archibugi and Pietrobelli 2003; Castells 1999; International Monetary Fund 2000). Yet, the very same progress has produced unprecedented risks, which are often uncertain and incalculable in nature (Giddens 1991; Beck 1986, 1999). Such 'uncertain risks' are usually associated with large-scale, long-term and transboundary hazards with which society has no or only limited experience (van Asselt and Vos 2008; van Asselt et al. 2009). As a result, their risk potential is highly contested. An exemplary uncertain risk is posed by genetically modified organisms (GMOs).[1] As it is contested whether GMOs constitute a risk to the environment and/or human health, scholars have pointed out that GMOs should be conceived of in terms of uncertainty (ibid.; Lang and Hallmann 2005; Levidow et al. 2005). Indeed, even though scientific or historical proofs of harmful consequences with regard to GMOs are lacking, "suspicions cannot be fully refuted either" (van Asselt and Vos 2008, 281). A decisive question is thus how to take decisions in the face of uncertainty (Beck 1999; Löfstedt, 2009).

The European Union (EU) plays a central role in addressing and dealing with uncertain GMO risks (van Asselt et al. 2009; Borrás 2006). GMO regulation in the EU constitutes a salient issue of risk governance, as the topic is politically highly visible and decision-making is slow and contested (Lee 2008; Renn and Walker 2007; van Asselt and Renn 2011). We understand risk governance as "the identification, assessment, management and communication" of potential hazards in the complex network that produces collective binding decisions (International Risk Governance Council 2007; van Asselt and Renn 2011). The supranational system of multi-level governance in the EU implies that authority is dispersed among many actors. Hence GMO regulation is in need of adequate mechanisms ensuring that decision-makers justify and account for their behavior (e.g.: Fisher 2004; Harlow 2002; Bovens 2007a). It has been pointed out that "the shift from national, state-based policymaking to transnational and multi-level European governance is not being matched by an equally forceful creation of appropriate accountability regimes" (Bovens

1 The term GMO refers to organisms whose genetic makeup has been restructured during the process of genetic engineering in order to alter an organism's behaviour, its growth potential or its resistance to diseases and pesticides.

2007b, 104; Harlow 2002). Lee (2008) demonstrates that the absence of accountability arrangements in the GMO regulatory framework constitutes a real gap. She argues that "who is responsible if things go wrong should be a key element of the regulatory regime for any new technology" (p.107).

The EU's political attitude towards GMO regulation has been described as precautionary (Wiener 2011; Cantley and Lex 2011; Klinke et al. 2006; Levidow, Carr and Wield 2005). Since the introduction of GMOs in Europe in 1997, Member States such as Austria, Luxembourg and Italy repeatedly imposed national bans on GM crops authorized on a European level. In spite of political controversy, the European Commission (hereafter the Commission) continued to advocate the approval of GM crops. The Commission's behavior arguably raises accountability concerns, which might ultimately result in declining legitimacy of the entire supranational system of risk governance (Skogstad 2011). In fact, Member States in the Council of Ministers (hereafter the Council) threatened with the rejection of any further authorizations until the regulatory procedures of the existing system are improved. Consequently, regulatory reforms took place between 2002 and 2004 and resulted in the present-day legal framework of GMO regulation.

Yet, important legitimacy and accountability problems of GMO regulation on the European level remain. While legitimacy aspects of GMO regulation have already been widely examined (e.g.: Borrás 2006; Skogstad 2003; Bengtsson and Klintmann 2010; Tiberghien 2009), accountability relations within the field of GMO regulation have hitherto only been weakly explored (e.g.: Skogstad 2011).[2] Nevertheless, it has been pointed out that "accountability on the EU-level remains fragile and is not secured by a comprehensive formal accountability arrangement" (van de Steeg 2009, 3).

In this paper we analyze who can be held accountable under the complex system of supranational risk governance with regard to GMO authorization, should uncertain risks materialize. In conjunction with this question, we examine why a certain actor can or even should be held accountable. In order to develop a theoretically and empirically informed answer to these questions, we apply a conceptual framework of accountability to the specific case of the authorization of Bt-11 maize[3] in the EU. The Bt-11 case covers different authorization

2 Skogstad (2011) examines difficult-to-reconcile conflicts between the internal accountability standards of Member State citizens and external accountability obligations to fellow WTO (World Trade Organization) members. Yet, we focus on the accountability relations between different actors within the process of multi-level EU risk governance.

3 Bt toxin has a deadly effect on various insects and is produced by the soil bacterium *Bacillus thuringiensis*: "by means of genetic engineering, the genes for the active agent (Bt toxin) can be transferred from Bt bacteria to plants" (GMO Compass, 2012a). Thus, Bt-11 maize is able to produce the insect toxin on its own which is meant to protect it from damage from certain insect pests and moreover "show tolerance to glufosinate ammonium herbicides" (Syngenta n.d., available online at http://www.infogm.org/IMG/pdf/snif_bt11_renew.pdf).

streams for i) food and ii) food and feed additives, each of which reveals different regulatory dynamics.[4] This allows for a thorough analysis of accountability relations with regard to different regulatory streams. We first present a conceptual framework of accountability. We then briefly outline EU regulation of GMOs in general and the two authorization streams of Bt-11 in particular. The case subsequently serves as the basis for the development a hypothetical scenario, which is used to assess accountability mechanisms. Eventually, this analysis may serve as a first step towards better understanding accountability relations within the EU authorization framework for GMOs.

We claim that the mere adherence to the regulatory procedures during the decision-making process does not necessarily imply that overall accountability can be secured, even though certain 'piecemeal' accountability may exist. The fact that overal accountability on the European level remains a delicate issue and may not be easily established within the framework of supranational risk governance can be related to Beck's (1999) notion of organized irresponsibility, which can be understood as the paradoxical situation in which contemporary society is incapable of dealing with long-term impacts of unprecedented risks notwithstanding sophisticated decision-making structures in place. Indeed, the complex system of interwoven rules can lead to a situation in which "a conviction is blocked by the very thing that was supposed to achieve it" (54): adherence to the regulatory framework can make it difficult to hold a single actor accountable and might even lead to a void of accountability. In order to test accountability relations within the multi-level framework of GMO regulation, it is, as Bovens (2006) has pointed out, imperative to establish under what conditions a certain arrangement in fact qualifies as a form of accountability.

2. Conceptualizing Accountability

Accountability is a contested and often elusive concept of which several definitions exist (Romzek and Dubnick 1987; Flinders 2001; Mulgan 2000; Scott 2006; Dowdle 2006) and it can have numerous meanings (Curtin et al. 2010). Accountability can be defined as a relationship between two parties: "A is accountable to B when A is obliged to inform B about A's (past or future) actions and decisions, to justify them, and to suffer punishment in the case of eventual misconduct" (Schedler 1999, 13). In this paper, the focus is on

4 Note that there is also a stream for iii) cultivation, which has, however, not yet been finalized and will not be discussed in this paper.

ex-post accountability: the actor has to render account after the event has taken place (Bovens 2007b, 108; Harlow 2002). So the question is whether actors involved in the authorization of Bt-11 might retrospectively be held accountable might risks materialize. We, furthermore, concentrate on public accountability: those who govern are accountable to those who are governed (Joss 2001). Depending on the forum, accountability can be classified as political (e.g. if the forum is a parliament), legal (e.g. if the forum is a court) or even administrative (e.g. if the forum is an administration such as the Court of Auditors) (Bovens 2007b, 108). Nevertheless, the *principal* forum in democracies is the public, which should ideally be able to scrutinize and judge the conduct of those who govern. Put briefly, for public accountability, also referred to as overall accountability,[5] to exist, it should always be possible to trace back the whole accountability chain to the principal forum, the citizenry. Accountability is thus defined in terms of an explicit actor-forum relationship (Bovens 2006, 2007a, 2007b). Bovens (2006, 10) argues that the relation between the actor and the forum has to be structured according to the following criteria in order to be qualified as overall accountability:

" (1) there has to be a relation between an actor and a forum,
(2) where the actor is obliged to inform about,
(3) explain and justify his conduct to the forum,
(4) so that the forum can interrogate the actor,
(5) question the legitimacy of his conduct
(6) and pass judgment on the actor's conduct
(7) which might lead to sanctions of some kind"[6]

It is important to emphasize that only when *all* these criteria are met, overall accountability is established. Yet, Bovens' criteria are not beyond criticism. Whereas van de Steeg (2009) argues that the possibility of sanctions is an essential element, Harlow and Rawlings (2007) point out that it may "rather than 'thickening' accountability, act as a deterrent by creating incentives to deny responsibility" (546). But in contrast to wider and less wel defined frameworks used by other authors (e.g.: Mulgan 2000; Behn 2001), Bovens' criteria al ow for a focused analysis: his criteria can be used as a kind of checklist. Although Bovens does not concentrate on the active process of holding to account, his accountability criteria can be employed to examine multiple accountability relations.

Our overall research question is therefore: who can be held accountable under the complex system of supranational risk governance with regard to GMO authorization in

5 Throughout the paper, we will employ the term overall accountability.

6 We read this as including the possibility of informal or soft sanctions, such as the loss of reputation.

general and Bt-11 in particular should uncertain risks materialize? In conjunction with this, two main issues need to be explored. First: to whom is account to be rendered? Thus, to which forum is an actor required to render account? Often accountability has to be rendered to numerous different forums (Bovens 2007a, 455). This is referred to as the *problem of many eyes*. Second: who should render account? Thus, who among the multiple actors involved has to appear in front of the forum? This has been called the *problem of many hands* as "policies pass through many hands before they are actually put into effect" (457). In the case of GMOs, several actors (many hands) as well as several forums (many eyes) can be identified. Through the case of Bt-11, we will analyze whether all conditions for overall accountability have been met. Are the identified actors accountable to the identified forums and are these forums able to pass judgment on the actor's conduct?

3. GMO Regulation in the EU

The present EU regulatory framework of GMOs is the result of regulatory reforms that took place between 2002 and 2004. In general, the authorization of GMOs is based on comitology, which is defined as "delegation of powers to the Commission and the supervision of the Commission's use of these powers through Committees composed of Member States' representatives" (Christiansen and Polak 2009, 5). The two key legal documents are Directive 2001/18/EC[7] on the deliberate release of GMOs (experimental or on the market) in the environment, and the Food and Feed Regulation (EC) 1829/2003.[8] The objectives include, among others, ensuring a high protection of human and animal health, taking account of environmental and consumer interests, but also providing for the proper function of the internal market. Regulation (EC) 178/2002 also defines the role of the European Food Safety Authority (EFSA), which serves as the independent scientific advisory forum to the Commission. The Commission's draft decisions on the authorization of certain GMO are forwarded to the Standing Committee on the Food Chain and Animal Health[9] (hereafter the Standing Committee). If the Standing Committee is unable to deliver a decision within 3 months or cannot reach a decision by qualified majority voting (QMV), the Commission decision is passed on to the Council. If the Council, too, is also unable to

7 Directive 2001/18/EC replaced Directive 90/220/EC.

8 Regulation (EC) 1829/2003 replaced the 1997 Novel Food Directive.

9 Consisting of representatives of all Member States and chaired by a Commission representative.

reach a decision by QMV, the authorization decision reverts back to the Commission.[10] The Commission is then in a position to take the final decision.[11]

3.1 Authorization of Bt-11 Maize

The authorization of Bt-11 is subdivided into three different streams (see Table 1). The authorization stream for cultivation of Bt-11 (Table 1 stream 1, not discussed in more detail) is still pending at the time of writing as the Council has yet to act. Bt-11 as food (stream 2) and Bt-11 as food and feed additive (stream 3) have been authorized for import and marketing in the EU. Due to our interest in ex-post accountability, we focus on stream 2 and 3.

Stream	1) Cultivation	2) Sweet Maize as Food	3) Food and Feed Additive
Scope	Cultivation, feed and industrial processing	Sweet maize as food (freshly or preserved) and food additives	Food and feed additives
Status	Risk assessment report	Valid authorization granted	Valid authorization granted
Relevant Legal Framework	Submitted under Directive 2001/18/EC (and under earlier Directive 90/220/EC). Application appropriately expanded in 2003.	The application was submitted under previous Novel Food Regulation (EC) 258/97. Assessment and licensing under Regulation (EC) 1829/2003.	Submitted under earlier Directive 90/220/EC and Novel Food Regulation (EC) 258/97. Valid license transfer. Renewal: Regulation (EC) 1829/2003
Application Date	1996 in France	11/02/1999 in the Netherlands	1996 in the UK
Decision	No QMV in Standing Committee referred to Council, which has yet to act	19/05/2004 (authorized by Commission Decision) until 18/05/2014	1998 (authorized by Commission Decision) until 18/04/2007
		Renewal in one single decision: 28/07/2010 (authorized by Commission Decision)	
Expiry date of authorization	Pending	27/07/2020	

Table 1 The different authorization phases of Bt-11 Maize divided by product use (Table by authors based on GMO Compass (2012b))

10 For an analysis of votings concerning GMOs in the Standing Committee and the Council, see: Navah, Versluis and Van Asselt, forthcoming.

11 Note, that under the new comitology procedures the Commission's ability to make the final decision has been limited (Council Decision 2006/512/EC and Treaty of the Functioning of the European Union, Art. 290 and 291).

Initially, the producer Novartis launched the authorization process of Bt-11 by applying for registration concerning food and feed additives (stream 3) in the United Kingdom (UK) in 1996. While the competent authority in the UK forwarded the dossier to the Commission with a favorable opinion, other Member States voiced their objections (Commission Decision 98/292/EC). Yet, on February 12, 1998, the Scientific Committee on Plants[12] concluded that "there are no reasons to believe that [...] [the] maize grain is likely to cause any adverse effects on human health and the environment" (preamble). Accordingly, the Commission decided in April 1998, that "consent shal be given by the competent authorities of the United Kingdom to the placing on the market of the following product, notified by Novartis Seeds Inc" (Art.1(1)) and "[t]he consent shall cover the placing on the market of the product to be used as any other maize grain but not for cultivation" (Art.1(3)). Following Art.5 of Regulation 258/97/EC, Novartis notified the Commission about its intention to place food and feed additives containing Bt-11 on the market.[13] This finalized the authorization under stream 3 for the time being.

After Novartis' fusion with Astra Zeneca, in February 1999, the company applied to the Netherlands under its new name Syngenta for placing Bt-11 as food on the market (stream 2).[14] The application was first examined by the Dutch competent authority. The Dutch risk assessment, released in May 2000, described Bt-11 to be as safe as conventional maize (GMO Compass 2012b). After the Commission had forwarded the risk assessment to the Members States, some raised reasoned objections (Commission Decision 2004/657/EC, recital 5). Following the favorable opinion of the Scientific Committee on Food with regard to the safety of Bt-11 maize (recital 9),[15] the Commission passed a draft decision to the Standing Committee. However, the Standing Committee was not able to agree with QMV (GMO Compass 2012b). Likewise, the voting in the Council resulted in a stalemate. Thus,

12 In the beginning of the authorization procedures of Bt-11, EFSA had not yet been founded. Risks assessments and opinions to inform draft decisions were carried out by EFSA's predecessors the Scientific Committee on Plants and the Scientific Committee on Food.

13 The product was included in a summary of notifications received by the Commission in Commission Notice 1999/C 181/15. After a valid license transfer, Bt-11 was referred to in a list of April 2005 concerning 26 authorized GM products that had been approved (or did not require approval) before the new legislative framework had come into effect (Europa Press Releases RAPID. Register of existing GM food and feed products published (IP/05/439)).

14 The application was submitted under the outdated Novel Food Regulation 258/97.

15 Validation studies were carried out by the Joint Research Center (JRC) of the Commission working in collaboration with the European Network of GMO Laboratories (ENGL). Recital (9) Commission Decision 2004/657/EC.

the proposal was returned to the Commission, which in May 2004 granted approval until May 2014 (Commission Decision 2004/657/EC).

In a comparable way, the Commission also decided on the renewal of authorization of Bt-11 food and feed additives, whose first-phase authorization expired in April 2007. On January 28th 2009 EFSA's GMO-Panel gave its favorable opinion for renewal (GMO Compass 2012b). Yet, as neither the Standing Committee nor the Council could reach QMV, the authorization was renewed by the Commission in July 2010 for the next ten years. The same decision also extended the authorization for Bt-11 as food until the same date, and thus combined the second and third stream into a single decision.[16] This implies that Bt-11, authorized in the EU since 1998 (stream 3) and 2004 (stream 2), can be used as food and as food and feed additive till mid 2020.

4. Testing Current Regulatory Regimes against Future Events

When investigating innovative technologies such as GMOs, it is important to note that innovation is in itself a 'generator of uncertainty' (Nowotny 2008). In such a context, developing scenarios is helpful to imagine future situations (Bishop et al. 2007; Børjeson et al. 2006; Groves and Lempert 2007; van Notten et al. 2003; van Asselt et al. 2010). A hypothetical scenario can serve as a tool to explore how uncertainties could play out in the future and what impact these might have on accountability relations with regard to supranational risk governance.

Notwithstanding the favorable risk assessments produced in the authorization processes, there has been substantial disagreement in the scientific community as to potential adverse effects of Bt-11 (e.g.: Prasifka et al. 2007; Hilbeck and Schmidt 2006). It is therefore reasonable to explore a hypothetical scenario in which such uncertain risks would materialize. On the basis of the Bt-11 case history, each juncture of the authorization process will be identified, including the actors involved and the accountability

16 Commission Decision 2010/419/EU (28 July 2010). By repealing Commission Decision 2004/657/EC that granted authorization of sweet maize as food, the Commission provided a single decision for: foods and food ingredients; feed containing, consisting of, or produced from Bt-11 maize; products other than food and feed containing or consisting of Bt-11 maize for the same uses as any other maize *with the exception of cultivation*.

relationships between them. While several forums can be identified, the public remains the principal forum to which account should be rendered. The scenario investigates who might be 'blamed' by whom, for what reasons, and whether the accused actor can be held accountable by the forum in accordance with Bovens' criteria. To structure the analysis, actors are grouped according to their roles envisioned in the regulatory framework (compare Ravetz 2001; van Asselt and Vos 2008): Syngenta as the risk producer, EFSA as the risk assessor[17] and the Member States, the Commission and the Council as the risk managers Risk management can be understood as "the process of deciding what appropriate actions to take in order to avoid, reduce, or eliminate a risk when there is (or might be) one" (Charnley and Rogers 2011, 364).. As also van Asselt and Vos (2008) have observed in authorization processes concerning other GMOs (i.e. NK603, GT73 and MON863 x MON810), in practice role ambiguity reigns. While Syngenta is naturally the risk producer, it also functions as risk assessor as a result of procedures and resources, due to which EFSA and its predecessors actually merely review the risk producers' risk assessments (EFSA 2011). Due to the political deficit (no QMV and hence technocratic decision-making) and the Commission's rubberstamping of EFSA's opinions, EFSA's role extends to that of a risk manager as will be elaborated below. Nevertheless the default roles serve as a useful guidance in the scenario development.

4.1 Hypothetical Scenario: Adverse Effects on Human Health

30 years after the initial authorization, the consumption of GM maize, including Bt-11 gene products, is linked to an outbreak of new food allergies. As warnings from the scientific community are getting louder, the media and non-governmental organizations (NGOs) are quick in picking up the topic and increase public awareness. Suddenly, retailers and the manufacturer find themselves under sharp attack. Consumers are highly worried and start boycotting most GM products. Similar to earlier food scares,[18] which are generally associated with "spiraling public anxiety over food safety incidents and escalating media attention that supplements such events" (Knowles, Moody and McEachern 2007, 43), consumer consumption and purchase behaviors are negatively affected. As a result, many retailers quickly withdraw GM products from sale. Fearing bad publicity and damage to corporate reputation, Syngenta immediately publishes a press release stating that

17 Risk assessment is a "procedure for including science in decisions about whether and to what extend risks to health, safety, or the environment should be limited" (Charnley and Rogers 2011, 362). Yet, "in nearly all cases the science, and hence the RA [risk assessment], is beset by uncertainties" (ibid.).

18 For instance the BSE crisis in 1996, the Dioxin scandal in Belgium in 1999 or the EHEC in Germany in 2011.

it adhered to all legal rules and procedures. The company also emphasizes that EFSA at the time endorsed Syngenta's risk assessment. Member States inform the Commission of the need to take emergency measures, using the Rapid Alert System for Food and Feed (RASFF).[19] The Commission reacts by recalling all products containing Bt-11 from the market.[20] Who can be held accountable under the complex system of supranational risk governance with regard to GMO authorization?

Risk Producer: Syngenta

Since the authorization process was initiated with an optimistic risk assessment by Syngenta, the first focal point is the company itself. International NGOs and the media are quick in denouncing the company for its apparent detrimental health impacts and question the credibility of Syngenta's risk assessment. In addition, some consumers seek to hold the company liable for damages occurred to them. In fact, the company's track record is not clean. Between 2001 and 2004, Syngenta mislabeled and sold unapproved and experimental Bt-10 as Bt-11 to US farmers, resulting in international public outbursts and corporate reputation damage (Herrera 2005; Bahnsen 2005). Yet, in this scenario it is unlikely that the company can be sanctioned, as Syngenta at the time of authorization adhered to all relevant legal procedures and the European authorities approved its risk assessment.[21]

Risk Assessor: EFSA

As EFSA endorsed Syngenta's risk assessments and disqualified Member States' reservations, it is likely to be asked to justify its decision. However, holding EFSA accountable may prove difficult if not impossible, due to its largely independent status (Vos 2005). When creating EFSA, the Commission failed to distinguish between two models of delegation:

19 The legal basis of the RASFF is Regulation (EC) 178/2002, which provides for emergency measures in case that food or feed (imported or of Community origin) constitutes a serious risk to human health, animal health, or the environment. Art. 50(2) states that if Member States or the Authority have "any information relating to the existence of a serious direct or indirect risk to human health deriving from food or feed, this information shall be immediately notified to the Commission under the rapid alert system".

20 In case the Commission would fail to take measures, the Member States would have the opportunity to "adopt interim protective measures" (Regulation (EC) 178/2002, Art. 54(1)).

21 Private corporate liability is indispensable for fair market conduct and safeguarding consumers' interests, but the liability debate falls outside the scope of this paper. We would, however, like to emphasize that adequate and strict liability mechanisms could provide for a serious financial incentive for risk producers to conduct a more rigid risk assessment in the first place. This is of particular importance with regard to EFSA's reliance on the initial information provided by the applicant company (EFSA 2011).

1) a mechanism under which EFSA is accountable to the Commission and 2) a clear emphasis on EFSA's independence on the other (Collins 2003). The resulting inconsistency is visible in official EU documents. While the White Paper on Food Safety superficially states that the agency should be both, independent and accountable to the European institutions (European Commission 2000, para.41), Regulation 178/2002/EC merely stresses the principle of independence (Art.37) and does not mention accountability. In this sense, accountability relationships are neither part of the institutional structures of the Commission "nor is it [EFSA] answerable to it [the Commission] with regard to the quality of its scientific advice" (Kuiper 2009, 394).

Art. 6(2) of Regulation (EC) 178/2002 states that the Commission is required to base its decision on scientific risk assessment. However, as the Commission lacks the necessary resources and scientific expertise to conduct such assessments, it has been argued that it is difficult if not almost impossible for the Commission to deviate from EFSA's recommendation (Christiansen and Polak 2009). With the Commission simply following EFSA's opinion, the functional separation between risk management and risk assessment becomes diluted. This has led to much criticism, as EFSA, now de facto both risk assessor and risk manager, is consequently in a position to yield considerable power over the authorization process (van Asselt and Vos 2008; Bengtsson and Klintman 2010).

Notwithstanding the above, there are three relevant forums to which EFSA *should* in principle render account: the Member States, the Commission and the public. First, EFSA should in principle be partly accountable to Member States. Yet, the fact that Member States are not represented in EFSA's Management Board and are thus not directly involved in scientific processes, reinforces EFSA's independence. Scholars have, however, pointed to the significant role of the Advisory Forum. The agency's Advisory Forum, which serves as a platform for the exchange of scientific information, is comprised of representatives of national food safety authorities of all EU Member States and has to meet at least four times a year (EFSA 2012a). The 'conflict clause' laid down in Art.30(4) of Regulation 178/2002 holds that "where a substantive divergence of scientific issues has been identified [...] the Authority and the national body shall be obliged to cooperate". Both representatives of the Commission and the European Parliament are free to join the Forum's meetings as stipulated by Regulation 178/2002, Art. 27(7). Moreover, Art.30(4) holds, that the Forum is supposed to "address contentious issues and diverging opinions" and, if no compromise can be reached, it has to submit to the Commission a joint document in which controversial scientific issues are clarified. While the Advisory Forum has been seen as the Member States' important link with EFSA's executive director, who chairs the Forum (Groenleer 2009), the director in fact does not answer to either the Commission or the Member States. Rather, he

is merely accountable to the board, which can remove him from office by a majority vote (ibid.). As such, the Advisory Forum has in practice a rather limited role. Consequently, one might argue that while EFSA should in principle be accountable to the Member States, EFSA is in fact *not* formally required to render account to Member States. While Member States are able to ask for explanation and justification concerning EFSA's risk assessment and EFSA is required to cooperate with Member States in case of diverging scientific opinions, Member States are in no position to pass judgment, leading to sanctions.

A second forum to which EFSA should be accountable is the Commission. In principle, even though the Commission lacks legal supervision, it is able to partly control EFSA's activities through its representation in the Management Board. EFSA's Management Board includes one Commission representative as well as 15 members appointed by the Council after consulting the European Parliament on the basis of a list drawn up by the Commission (EFSA 2012b). In addition, the Commission "sees a role for itself in the approval of the annual reports, the budget and the financial control" (Vos 2005, 128). However, the fact that EFSA only delivers non-binding opinions based on its risk assessment implies that the agency does not necessarily need to provide justification concerning its risk assessment, as it is ultimately the Commission's decision whether to follow EFSA's advice. As EFSA's role as risk assessor is thus in principle divorced from the Commission's role as risk manager, EFSA is indeed *not* answerable to the Commission. In case uncertain risks materialize, EFSA may argue to be merely the risk assessor and that it is ultimately up to the Commission's judgment whether or not to follow EFSA's advice. While the Commission may question the legitimacy of EFSA's conduct, it is unable to pass judgment, leading to sanctions. At best, a loss of reputation concerning EFSA's credibility might occur.

Third, the last and most important forum is the public. Regulation (EC) 178/2002, Art.10 clearly assigns the duty to EFSA to inform the public in a transparent manner concerning potential risks stemming from food products. In particular, Art. 38 holds that EFSA should make public without delay "(a) agendas and minutes of the Scientific Committee and the Scientific Panels (b) the opinions of the Scientific Committee and the Scientific Panels immediately after adoption, minority opinions always being included (c) information on which its opinion is based." In addition, the Regulation requires EFSA to guarantee the inclusion of concerns of relevant stakeholders and develop "effective contacts with consumer representatives, producer representatives, processors and any other interested parties" (Art. 42). The agency has created online public consultation forums, in which members of the public and interested parties can express concerns with regard to specific scientific issues and submit relevant information and data (EFSA 2012a). Yet, even though the agency has developed a relatively open structure of public consultation procedures

and has willingly provided information in a transparent manner during the authorization process of Bt- 11, the public is unlikely to be able to ask for justification or to actively interrogate EFSA. Indeed, while the public may question the legitimacy of EFSA's conduct in case uncertain risks materialize, it is in no position to pass judgment, leading to sanctions.

In sum, although EFSA is a highly influential body due to its role as risk assessor and de facto risk manager, it seems to be hardly accountable to any forum. In case uncertain risks materialize, EFSA may refer to its primary de jure role as merely risk assessor and ignore its de facto role as risk manager. Although in regulatory practice a 'grey zone' between risk assessment and risk management has emerged, the strict separation between risk assessment and risk management is inscribed in the regulatory framework (Vos and Wendler 2006). This is likely to be emphasized by EFSA to reject responsibility and it might well be an effective defense.

Risk Managers: Member States, the Commission and the Council

Member States, the ministers in the Council and the Commission are other important actors during the authorization process of Bt-11. Member States were involved in the authorization process by voting in the Standing Committee and in the Council. In principle, Member States are accountable to their public, as national voters through parliaments can hold national ministers to account for their conduct in the Council (Gallagher et al. 2005). Yet, considering the time passed between the initial authorization and the outbreak of food allergies, the term of office of the responsible ministers is likely to have already elapsed. In theory, their successors are accountable for all their acts, but in practice it might be more difficult to hold individual ministers to account, e.g. when their party affiliations are different or the new minister was a critical MP at the time of authorization.[22]

During the authorization for Bt-11 as food, the vote in the Council resulted in a stalemate. The decision therefore reverted back to the Commission who in turn decided to rely on its initial draft proposal and subsequently authorized Bt-11 for consumption. This complicates the situation as the final decision was made by a technocratic body which is not as accountable as national ministers would be. The Commission inevitably took a decision not endorsed by QMV in the Council (van Asselt and Vos 2008; Christiansen and Polak 2009), which situation van Asselt and Vos (2008) qualify as a political deficit.

In principle, the Commission is accountable to the European Parliament (EP) as well as to the public. Although the European Parliament is not involved in the decision-making

22 It is beyond the scope of this paper to review the academic literature on (political) accountability at the national level in view of this elapse of term of office.

process of GMO authorization, it may retrospectively still act as an important forum to give voice to the European citizens.[23] Van Gerven (2005) shows that under current Community Law "members of the Commission are bound to explain their action to the European Parliament, and they can be held accountable by Parliament when those actions constitute wrongful behavior" (83). The European Parliament's right to interrogate Commissioners is stated in Art.230 of the Treaty on the Functioning of the European Union (TFEU): "The Commission shall reply orally or in writing to questions put to it by the European Parliament or by its Members". Moreover, the European Parliament is able to censure the Commission according to Art.234 of the TFEU, or even force the whole body of the Commission to step down.[24] Here again, the problem is that the term of office of the Commissioners responsible for the authorization might already have elapsed. So the accountability relationship between the Commission and the European Parliament in case of future materialization of uncertain risks seems weak.

Admittedly, the public has the opportunity to make comments to the Commission following the publication of EFSA's opinion as stated in Regulation (EC) 1829/2003, Art.6(7). However, "neither the scope nor the salience of such comments is outlined" and the Commission is "not specifically mandated to take these [comments] into account" (Scott 2004, 20). In fact, the Commission is merely required to take into account EFSA's opinion. Only if the Commission's recommendation on authorization differs from EFSA's opinion, explanations of the underlying reasons are indispensable (Skogstad 2011, 9). Yet, this was not the case regarding Bt-11 as food and food and feed additives (stream 2 and 3). As a result, the public is retrospectively not in a position to ask for explanation and justification or to actively interrogate the Commission. While it may question the legitimacy of the Commission's conduct, it is unable to pass judgment, leading to sanctions. As such, accountability relations between the Commission and the public are as good as nonexistent.

The members of the Council are individually accountable to the public and their national parliaments. However, since the emergence of majority voting with the Single European Act of 1986, in their national parliaments, ministers are able to justify taken decisions by claiming that they did their best to secure a particular policy, but were outvoted (Bogdanor 2007). While this of course does not always happen, in principle,

23 This has been demonstrated by the European Parliament's inquiry report with regard to the management of the EU BSE crisis (European Parliament, 1997).

24 In 1999, for example, the Santer Commission was successfully pressured into resigning after having been accused of serious mismanagement and corruption.

an individual minister "cannot be made accountable to his or her national parliament for a decision that has been taken by others" (6). Nevertheless, the Council missed the chance of representing Member States' interests (and thereby national public's interests) by having been unable to reach a compromise and left the decision to an unelected and bureaucratic body. This political deficit, which was already undermining the legitimacy of the decision (Borrás 2006) might thus have severe consequences also in view of ex-post accountability. Here again, the public as the principal forum is in a difficult position to hold the Council to account. Only national parliaments are able to ask for explanation and justification and to actively interrogate the Council. While both the public and national parliaments might question the legitimacy of the actors' conduct, neither of the two forums is in a position to pass judgment, which might lead to sanctions. At best, informal sanctions might entail a loss of reputation. Thus, at the supranational level, accountability relationships get diffused, which relates to the problems of many hands and many eyes, as regulatory decisions pass through many hands before being implemented, and as account has to be rendered to numerous forums. However, none of the forums seem able to pass a judgment and sanction in case uncertain risks of Bt-11 would materialize in the way envisioned in this scenario.

5. Conclusion

We attempted to explore accountability relations within the supranational multi-level framework of GMO risk governance by means of a hypothetical scenario on adverse effects associated with GMOs in general and Bt-11 in particular. Informed by the regulatory history and state of affairs pertaining to Bt-11, we tested current regulatory standards and future events against the accountability criteria as developed by Bovens. We focused on ex-post accountability to assess whether actors can be retrospectively held accountable: do the rules, regulatory procedures and institutional arrangements sufficiently provide for accountability in case that the outcome of the decision-making process is not satisfactory? While legitimacy of GMO regulation has frequently been discussed in the academic literature, accountability issues are rather underrepresented. Still, as accountability is a necessary prerequisite for legitimacy, its significance should not be underestimated. Decreased accountability may lead to weaker legitimacy.

Our findings can be summarized in three points: First, each actor in the authorization process can at best be partly held accountable for his conduct. Hence, overall accountability cannot be established. Second, each actor is able to point to its compliance with the legal

rules and procedures of GMO regulation at the times of authorization, which makes it difficult to pass a negative judgment. Third, each actor can refer to the involvement of other actors in reaching the final decision, by which the 'blame' can be shifted to other actors in the accountability chain. In sum, these points reflect Beck's hypothesis of organized irresponsibility: a situation where regulatory structures are unable to sufficiently address negative consequences and long-term impacts, notwithstanding that most actors adhered to the rules and procedures in place. Yet, we do not claim that no accountability is in place, as 'piecemeal accountability' can be established. We suggest the notion piecemeal accountability for situations in which one or more, but not al of the seven Boven's criteria are satisfied. In European GMO regulation, overall accountability, with al Bovens' criteria met, is not in place.

With these findings, we are able to demonstrate that uncertain risks resulting from technological progress and innovation pose a particular governance challenge. The current system of European GMO regulation is unable to sufficiently hold actors accountable, should uncertain risks materialize. This adds an important dimension to ongoing scholarly and societal debates on risk governance. Our scenario-informed reflection based on the authorization of one GMO provides a basis for agenda-setting the issue of accountability and for arguing that this kind of scenario thinking is productive to explore accountability relationships. It does, however, not provide a sufficient basis for concrete suggestions what is needed to improve accountability relations in the EU risk regulatory system. But it is clear that in the current European regulatory framework on GMOs in particular and probably on innovation induced risks more generally, the pursuit of accountability relations is simultaneous necessary but difficult to achieve.

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Similar Risks – Different Results

Analyzing the Inconsistent Application of the Precautionary Principle in European GMO Authorization

Lukas Jochum, Simon Reetz, Nicole Rode, Lea Tries

Table of Contents

1. Introduction

"Sometimes it is much better to be safe than sorry" (Sunstein, 2003, p.1019). This proverb represents the essence of the precautionary principle (PP), which became salient in Western German environmental policy during the late 1970s, when policy-makers saw the explicit need for a so-called *Vorsorgeprinzip* for the first time (Fischer, Jones & von Schomberg, 2006, pp.2- 3). Nowadays, the PP is widely used in national, as well as international law, yet also heavily criticized. The principle legitimizes to take actions in situations of scientific uncertainty,[1] in which risks and their respective probabilities are unknown. Some academics claim that the PP is a no-risk- and non-science based principle (see e.g. Fischer, Jones & von Schomberg, 2006; Haritz, 2010; Rogers, 2001; Victor, 2001; Zander, 2010). It is often even deemed as a "paralyzing" principle (Sunstein, p.1004) that leads to overregulation (Löfstedt, 2004) and encourages regulators to only focus on one risk while forgetting that we live in the "real world of multiple risks" (Wiener and Rogers, 2002, p.322). Nevertheless, by many this principle is esteemed as providing safer regulation, arguing that criticism should rather be directed at its implementation and operation in practice (Fischer, Jones & von Schomberg, 2006).

In the European Union (EU) the use of the PP has been described as leading to inconsistent and arbitrary decision-making by academics (Zander, 2010), industry (Monsanto, 2011) and policy-makers (Bundesministerium für Ernährung, Landwirtschaft und Verbraucherschutz [BMELV], 2011). According to Zander, "similar situations are not treated in a comparable fashion, which makes it increasingly difficult to foresee how and when precautionary measures wil be applied" (p.327). Consequently, there is a risk of unfair and incoherent regulation, impeding further Research and Development (R&D) and preventing citizens from being properly protected against real risks. Furthermore, the arbitrary use of the PP by certain Member States (MS) leads to distortions in the internal market (Zander, 2010).

Due to the public's distrust of science and governmental regulation of food and feed resulting from the BSE crisis (Victor, 2001), the PP has become highly important for regulation of genetically modified organisms (GMOs) in the EU. Particularly in the field of GMO authorization, the use of the PP in the EU has been frequently criticized for its incoherence and lack of transparency (Wiener and Rogers, 2002; Zander, 2010). Accordingly, an in-depth analysis of example authorization procedures can give insights in how to improve the PP's application in practice.

1 It should be noticed that science can never provide absolute certainty (see e.g. Zander, 2010).

Since this can only be realized within an improved procedural framework, this article seeks to further develop the so-cal ed "procedural precautionary principle" (see e.g. Fischer, Jones & von Schomberg, 2006; Haritz, 2010; Zander, 2010) by creating a 'tool-box' for the analysis of the PP in practice. This tool-box will be applied to the analysis of the authorization procedures for cultivation of MON810 and Bt11 in the EU. While both GMOs contain the same Bt-protein, the policy outcomes of these two authorization procedures were quite different. MON810 was approved for cultivation in the EU, whereas the authorization procedure of Bt11 is currently stalled. The question thus arises why in two cases of similar situations of uncertainty, the policy outcomes varied considerably. The incoherent application of the PP in the two authorization procedures seems to constitute the problem.

However, the analysis of the respective authorization procedures suggests that the answer to this question goes beyond pointing to inherent flaws of the PP. Rather, the lack of a uniform perception of the PP, and particularly the deficient procedural framework of it in the EU constitute the problem. By presenting two scenarios developed based on the analysis of the case studies of MON810 and Bt11, this article will depict how the authorization procedure for GMOs in the EU could become more coherent, comprehensible and reliable, as well as more effective. This article therefore adds to the current scientific and political debate surrounding the principle by further developing the procedural version of the PP and by designing scenarios which can help to evaluate current regulatory developments and improve the application of the PP in the field of GMOs.

First, the methodology used throughout the analysis wil be explained. Second, the PP's relevance in EU legislation as well as the different versions of the PP will be elaborated on before turning to a procedural PP developed for the analysis of the subsequent case studies. Afterwards, the authorization procedures of MON810 and Bt11 will be examined by means of the procedural PP. Based on this analysis two scenarios on the future use of the PP in the EU authorization procedure for GMOs will be presented. Lastly, a short conclusion will sum up the findings of this article.

2. Methodology

The main question this article seeks to answer is *why*, facing virtually the same situation of scientific uncertainty, the authorization procedures for cultivation of Bt11 and MON810 have taken such different paths. In the course of this article, the focus will be largely on *how* the PP has been applied in the relevant cases and whether this influenced or even caused incoherent decision-making.

Founded on an extensive literature review on various perceptions of the PP, the theoretical framework will be based on the three different versions of the principle suggested by Wiener & Rogers (2002, pp.320-1). However, due to the difficulty of identifying these neatly subdivided versions of the PP within the complexity of the EU multi-actor framework, this article complements Wiener & Rogers' approach with a practical, application-based view of the precautionary principle[2] – a procedural PP – which allows pinpointing the exact differences in how the PP was applied, by breaking the principle down into several smaller features. Moreover, this conceptual framework will also serve as a 'tool-box' to 'build' future scenarios, proposing how to avoid similar situations in future.

The choice of methodology that one uses for research largely depends on the research questions that are asked (Berry, 2002, p.673). While every type of research method has its specific qualities, "case studies are the preferred strategy when 'how' or 'why' questions are being posed" (Yin, 2009, p.1). Additionally, Yin states that case-studies are generally the best choice if the researcher cannot control the events being studied, and when the subject of study is a 'contemporary phenomenon with some real-life context" (ibid.). Moreover, al types of evidence, such as documents, interviews, observations etc. can be included in the study (p.8), which is why Yin refers to the case study as an "al -encompassing" and "comprehensive" research method (p.13).[3] The case-study research will be largely based on desk-research techniques, yet to triangulate, this article also employs interviews in order to increase the reliability[4] of the data used (p.14).

The design of an interview-study can vary greatly and depends on the purpose it functions in the overall study. Aberbach and Rockman (2002) point out that when the goal of an interview study (as it is in this case), is to fill in knowledge gaps or collect specific opinions, it is advisable to select specific subjects for interviewing (p.673). Naturally, when evaluating the findings of interviews, it is crucial to be aware of inherent shortcomings with regards to the reliability, validity and objectivity of the data obtained (Berry, 2002, p.680).

Based on the findings of the case study, two possible future scenarios will be developed. The inclusion of the scenario approach adds to the current scientific repertoire of risk research, as scenarios can be employed to "explain possible futures in a structural way" (Fox et al, 2011, p.38), yet they are currently not applied frequently in the study of riskmanagement and evaluation (van Asselt et al., 2010). Especially in the field of the PP, rarely ever are the suggestions which are brought forward in the academic literature really applied or tested.

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2 For more information see: Haritz, 2010.

3 For more information see: Yin, 2009.

4 For more information see: Berry, 2002; Aberbach & Rockman, 2002.

Therefore, in this case, two scenarios will be developed, both serving different purposes. The first scenario is based on an extrapolation of current developments in the area of GMOregulation. This 'Commission scenario' is based on "what wil happen if the most likely development unfolds" (Börjeson et al., 2006, p.726). The second scenario wil function as an 'alternative' version. It incorporates the findings from the analysis of the application processes and designs a functional procedural version of the PP for the area of GMO risk regulation that can reconcile MS, Commission, stakeholder and WTO concerns.

In short, this approach not only makes it possible to analyze what went wrong in the policy process, but moreover points towards the possible consequences of current reactions to the problems identified, and further develops and applies an alternative solution instead.

3. Precautionary Principle

This section elaborates on the application of the PP in the EU and introduces as well as criticizes different versions of the PP. The intention of this section is not to present an exhaustive overview of the academic debate on the PP, but rather to become familiar with a prudently chosen interpretative framework for the PP's application, relevant to the analysis of the following case studies, as well as to the development of the final scenarios.[5]

3.1 Precautionary Principle in the EU

With the Maastricht Treaty the PP was incorporated into EC law (Fischer, Jones & von Schomberg, p.10). The principle is included in Art. 191(2) TFEU, stipulating that the EU's environmental policy must be based upon the PP, yet without giving any definition of the principle. In 2000, the European Commission published a Communication on the PP (European Commission, 2000) with the intention to make its implementation more coherent (Fischer, 2002, pp.8-9). However, a clear definition of the principle was still not given.

Nevertheless, the Commission stated that it was "wrong to conclude that the absence of a definition has to lead to uncertainty" (European Commission, 2000, p.1). Until now the only attempt to define the PP within the legal framework of the EU can be found in Art.7(1) of Regulation EC/178/2002, commonly known as 'General Food Law', which was created in

5 For an extensive debate on the PP see e.g. Sandin, P. (1999). Dimensions of the Precautionary Principle. *Human and Ecological Risk Assessment, 5*(5), .889-907 and O'Riordan, T., Cameron, J., & Jordan, A. (Eds.). (2001). *Reinterpreting the Precautionary Principle*. London: Cameron May International Law & Policy.

response to the BSE crisis. This clearly shows that the application of the PP is no longer confined to the field of environment but has also found its way into food safety, including GMOs. Furthermore, the PP is a "general principle of Community law", and hence a legally binding rule in the EU (ECJ, 2002, para.184).

Nevertheless, the WTO's stringent application of the PP has to be considered too. The diverging interpretations and applications of the principle, particularly in the field of GMOs, have led to trade disputes between the EU and the WTO before. On the WTO level the PP is incorporated into Article 5.7 of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) (ECJ, 2002, para.184).It is of particular importance that Article 5.7 is read in conjunction with Articles 5.1 and 5.2 of the agreement, as for example, in the EC Biotech case, the WTO Panel ruled that the PP cannot be used to obviate a risk assessment (WTO, 2006).

3.2 The Procedural Precautionary Principle

This section will introduce an interpretative framework to be used in the following analysis of the case studies and in the development of the scenarios. Wiener and Rogers (2002) distinguish between three "versions" of the PP, in ascending order regarding its strictness: 1) "Uncertainty does not justify inaction", 2) "uncertainty justifies action" and 3) "uncertainty requires shifting the burden and standard of proof."

The first version of the PP can be found for instance in the Bergen Declaration of 1990. It allows for action, however, it does not give an answer to the question "what action to take, given inevitable uncertainty" (Wiener and Rogers, 2002, pp.320-1). The second version is more aggressive since it does not only imply that there is a "right to act" but also that there is a "duty to act" (Haritz, 2010, p.144). Nevertheless, it does not provide regulators with information on how precautionary action should look like, either. One example of this "proactive version" (ibid.) can be found in the Wingspread Statement of 1998. According to Haritz, the actions taken following from either the first or second version of the PP depend on "the social, economic, cultural and legal settings" and the "respective policy area" where they are taken (p. 138). The third, most aggressive version suggests explicit action. However, its application might lead to overregulation and is seldom used in practice (Wiener and Rogers, p.321). Haritz claims that the definition of the PP in the Third International Conference on the Protection of the North Sea, as well as the use of the PP in the EU come close to this third "risk- minimizing" version (p.144). However, it is arguable whether the PP used in the EU is risk- minimizing or rather proactive and usually varies on a case-by-case basis. The three versions of the PP vary in the degree of action that might be taken in cases of uncertainty. In the following case studies, however, the focus

will be on different perceptions of the threshold levels of uncertainty necessary in order to take precautionary actions. Wiener and Rogers' three versions of the PP are nonetheless very helpful as a theoretical framework for this article, since the degree of an action and the degree of uncertainty are closely entangled, and it is almost impossible to clearly distinguish between those two elements when the PP is applied in practice.

Based on the analysis of Wiener and Rogers' three versions of the PP, Haritz, stresses the need for a procedural PP that would provide a framework for decision making as well as the procedure for invoking the principle, in which the burden of proof would be shared by the regulator and the applicant. This fourth version of the PP would complement one of the three versions of the principle presented above and make its application not only operable but also more democratic (pp.146-9). The need to have a procedural framework for applying the PP has also been stressed by Fischer and Harding (2006). They argue that the application of the PP cannot be solved by a "prescribed formula or quantified algorithm", but only by an institutional structure developing a flexible process adapted to the problem (p.123). Without such a procedural framework, they conclude, the PP's application in the EU seems to be arbitrary. Nevertheless, one has to take into account that different legal cultures provide for different legal frameworks and procedures in different judicial systems (ibid.).

4. A Tool-Box for the Procedural Precautionary Principle

Academic scholars and political working groups have presented many attempts of analyzing the procedural version of the PP by breaking it down into smaller, tangible features that play into how the principle is implemented in the policy-making process (van Dijk et al, 2011; Mbengue & Thomas, 2004; Cheyne, 2006). These findings however tend to be rather narrowly focused on few aspects of the application-process and thus often fail to grasp all facets of the PP in risk management. This article adds to these attempts by structuring the different procedural facets of the PP according to two rather broad poles: the '*narrow*' and the '*open*'. This juxtaposition facilitates the analysis of case studies according to a set of characteristics and allows to subsequently draw conclusions about the pitfalls and inconsistencies that lie at the bottom of the authorization procedures. Moreover, the procedural breakdown of the PP will further serve as a basis

for the scenarios, which are developed later in this article. The debates surrounding the application of the PP in a procedural framework have evolved along five issue areas, which often overlap and are to a large extent interdependent.[6]

4.1 When to apply the Precautionary Principle

The first issue is whether the PP should be regarded as a 'decision-rule' or as a 'strategy'. According to van Dijk et al, using the PP as a strategy "in each step of the [decision-making] process" (2011, p.5), prevents arbitrary regulation in the risk management phase only (2011, p.4). Gardiner, however, has suggested that a 'purely procedural PP' offers no directional advice and thus no guidance in decision-making (2006). Adding to this criticism, Cheyne has stated that the risk-evaluation phase is the appropriate situation to employ the PP, hence allowing for a higher degree of objectivity in the phase of scientific assessment and the choice of an adequate policy response (2006, p. 843).

Nonetheless, Motaal has suggested that in practice, it might be impossible to limit the PP to certain phases of the decision-making process, as scientists often already implicitly apply the principle in risk assessment by using 'inference options' which prioritize an over- or underestimation of risks (2005, p.495). Therefore, it will also be important to look at how the different phases of risk regulation are connected. While in practice, risk assessment and management are often perceived as separate steps (Cheyne, 2006), van Dijk et al. point out that it is in fact "not a simple linear series of separated steps", as new issues may arise at any point in decision-making, leading to a back-and-forth process between the stages (p.5).

4.2 Level of Codification

A second source of disagreement, particularly among legal scholars, has been the degree of codification that is needed for an effective application of the PP. On the one hand, it has been claimed that only a precisely defined version can lead to effective and coherent policy-making (Perez, 2006, p.6). On the other hand, scholars have argued that a rather broad interpretation can make the PP better applicable and in fact more effective (Faure & Vos, 2003), suggesting that the former may block scientific progress.

4.3 Basis for the Use of the Precautionary Principle

A third area of controversy has been whether the use of the PP should only be mandated by scientific evidence, or whether it should be politicized. Perez has stressed the "important

6 Not all characteristics will be analyzed in the article, but are included here for the sake of developing a comprehensive theoretical framework.

political facets of the precautionary principle", claiming that science cannot determine the acceptable risk- level for society and that only politics can reconcile scientific, societal and economic pressures (2006, p.17).

This conviction is related to van Dijk et al.'s finding that even recommendations by Scientific Advisory Bodies are "inherently political" (Van Dijk et al., 2011, p.11). Therefore, rather than giving policy recommendations, the authors argue that such bodies should only have the task of "map[ping] the decision situation" by presenting all available evidence and al possible interpretations of the uncertainties, while acknowledging the value-judgments that have played into the respective interpretations (p.12). This would inform decision-makers scientifically, without precluding decisions.

The end of strictly science-based decision-making in turn would allow for an increased participation of stakeholders in the process. Van Dijk et al. point to a demise of traditional technocratic regulatory regimes, as "governments increasingly seek to arrive at policy decisions in consultation with stakeholders" (2011, p.5). The authors are convinced that the inclusion of the stakeholders' diverse set of expertise can enhance the quality of the decisions, but that such participation would also necessitate strict procedural rules (p.6).

The degree to which stakeholders can take part in the regulatory process also depends on the emphasis that is put on the inclusion of 'objectivity' requirements when invoking the PP, such as cost-benefit analyses or proportionality tests (Motaal, 2005, p.485). While proportionality requirements have been applied frequently in WTO-rulings (Cheyne, 2006, p.852) and ECJ case law (Rogers, 2011, p.475), the ECJ has rarely ever mentioned the necessity of cost-benefit analyses, although set out in the 2000 Commission Communication (Rogers, 2011, p.478). On the contrary, by not relying on such 'objective' factors, policymakers would have the possibility of including societal concerns in their decisions. Critics believe the inclusion of such concerns would cause the principle to be unreliable and incoherent (Sunstein, 2003). Contrarily, van Dijk et al. have argued that societal input might lead to more acceptable results, by increasing transparency and accountability of decisions (2011, p.6).

Eventually, the role of science also determines the provisional nature of the PP. Rogers (2011) has pointed out that despite its importance for the principle, the temporary status "has had only limited impact on the PP" in the EU (p.479). In practice, any preliminary negative decision often discourages further research and investments in products (p.480). Rogers thus stresses the importance of time-frames and further scientific research on the product in order to support any provisionally taken decision.

4.4 Dealing with Information

It is wel established that "scientific evidence itself is not always neutral, determinative or uniform" (Cheyne, 2006, p.838). In the area of risk-regulation there are thus diverging interpretations of scientific facts. Dominant views have often been referred to as 'majority' science, while less common interpretations have been termed 'minority' science (Motaal, 2005, p.487). While the inclusion of such minority science has been a contentious issue in risk regulation, both, the WTO (Mbengue & Thomas, 2004, p.8) and the EU[7] have shown the will to allow the use of minority opinions when invoking the PP, as long as they are based on sound scientific evidence.

Additionally, the statement above implies that *all* scientific results are subjective (Cheyne, 2006, p.838). The questions raised due to this erosion of the classical positivist view on science are mostly concerned with the possible added value the inclusion of subjective views into the risk assessment phase (van Dijk et al., 2011, p.6).[8]

4.5 Risk Communication

The issue of communication influences the application of all aforementioned variables, which is why van Dijk et al. refer to it as "the center piece of sensible risk governance" (2011, p.6). Recalling the intended procedural tool-box, a distinction between rather closed (i.e. dialogue between regulators and scientists only) and more open applications of the PP (i.e. communication amongst all stakeholders) can be drawn. More recently, several scholars have advocated the opening up of the risk communication process, arguing that "if the actors shared their knowledge and experience it is self evident that the likelihood of reaching more optimum risk management decisions when faced with uncertain science would be increased" (Rogers, 2011, p.481). This argument is based on the hope that an open information policy could lead to a convergence of views. However, even proponents of such an approach acknowledge that it cannot solve all disputes (ibid.). Especially the communication to the public is a difficult balancing act between creating transparency and assuring public trust and confidence in experts (van Dijk et al., 2011, p.6).

4.6 Two Ends of the Same Spectrum

Based on the multitude of issues revolving around the PP, this article provides a table which classifies these characteristics according to two rather broad poles of application. Both sides do not represent absolute categories, but two ends of the same spectrum of how the

7 See: Art. 38(1), Regulation 178/2001/EC.

8 For more information see: Mbengue & Thomas, 2004; Cheyne, 2006; Van Dijk et al, 2011.

principle can be applied in practice. It is not the aim of this classification to provide a new set of definitions for the PP. Moreover, features from both sides are not necessarily contradictory. In fact, it is likely that any PP version used in practice will combine characteristics of both sides.

INTREPRETATIONS/APPLICATIONS OF THE PP	
WHEN TO APPLY THE PP	
Narrowly interpreted Legal Principle	Flexibly treated Governance Principle
precautionary principle in Risk Management Phase only	precautionary principle as strategy throughout decision making process
Linear Process/Strict procedural rules	Back and forth communication among all involved actors
LEVEL OF CODIFICATION	
Codified in one binding definition	Considered as Customary law, accounting for complexity and flexibility in application
DECISION MAKING	
De-politicized	Politicized
Scientific advisory bodies as de-facto decisionmakers, providing one clear policy-recommendation	Scientific advisory bodies as advisors only, providing all possible interpretations of the scientific data
Inclusion of 'Cost-Benefit', 'Proportionality' and other requirements	No objectivity-requirements
De-facto permanent decision-making	Temporary decision-making (stressing time-limitation and the need for more scientific evidence)
DEALING WITH INFORMATION	
Scientific information only	Subjective information, societal concerns included
Use of Majority scientific opinions only	Recognition of Minority scientific opinions as valid reasons to invoke precautionary priciple
COMMUNICATION/STAKEHOLDER INVOLVEMENT	
Policy-makers (Risk Managers) and Scientists (Risk Assessors) only	Involvement of all Stakeholders throughout decision making process
Communication based on stalemate of opposing scientific opinions (no progress, eventual decision in favor of one or the other, often in Court)	Open Communication process in order to develop a common understanding of the risk-scenario

This tool-box intends to provide the procedural PP with analytical substance, thus complementing the rather rigid and theoretical versions developed by Wiener & Rogers. Analyzing the application of the PP based on the aforementioned procedural and practical factors allows the researcher to determine which conceptual versions of the PP were used in the analyzed cases, and pinpoint the pitfalls in the applications of the principle.

5. Precaution in Authorization Procedures of GMOs in the EU

Based on this theoretical framework, the following section analyzes the MON810 and Bt11 application processes and draws conclusions on how the PP has influenced the respective outcomes.[9]

9 Currently, it is possible to file an application for cultivation of GMOs under two different regimes, Regulation 1829/2003/EC and Directive 2001/18/EC, which repealed Directive 90/220/EC. The main aim of both pieces of legislation is to create a standardized authorization procedure for GMOs throughout the EU and provide for greater public confidence in GMO releases due to more transparency (European PPP Expertise Centre, 2009). A detailed description of the concerned procedures goes beyond the scope of this paper and is referred to only when necessary.

5.1 Case Studies

In the following section the application of the PP in the EU will be examined at the example of the authorization procedures of two different GM crops: MON810 and Bt11.[10] Both cases are concerned with ordinary maize which is genetically modified in such a way that it is resistant against certain pests, especially the European corn borer. This is achieved by transferring the *Cry1A(b)* gene from a particular bacterium into the maize by means of genetic engineering. Next to the *Cry1A(b)* gene, Bt11 maize contains another gene which increases the plant's tolerance to a main component of many herbicides. In both cases, the possible resistance of target species against the Bt-toxin and the unintentional effects of this toxin on non-target organisms, particularly larvae of other insects, have been identified as an uncertain risk involved in cultivation (EFSA, 2005). Yet, since 1998, MON810 can be legally cultivated in the EU while the authorization of Bt11 is still pending.

5.1.1 MON810

5.1.1.1 Authorization of MON810

On 24 May 1996, pursuant to Art.5(1) Directive 90/220/EC, Monsanto Europe applied for the authorization for a genetically altered maize called MON810 with the French Competent Authority (Dolezel et al., 2007). The notification was subsequently forwarded to the Commission and the other MS (European Commission, 1998, rectial 5). After several MS objected to the intended labeling and monitoring of the crop, the applicant made amendments to its application (recital 6). In line with Art.13(3) of Directive 90/220/EEC, the Commission requested a scientific opinion from the Scientific Committee on Plants (SCP) for advice and comments on the objections of the individual MS to be taken into account. However, it can also be observed that merely policy-makers and scientists had a say in the process, whereas other stakeholders, such as environmental organizations were not involved directly.

In its opinion the SCP concluded that there is "no evidence to indicate that the seeds of [this] insect-resistant maize [...] when grown, imported and processed in the manner indicated, are likely to cause adverse effects on human or animal health and the environment" (SCP, 1998). Furthermore, the SCP stressed the fact that the Bt-toxin produced by MON810 had been used as an agricultural pesticide against certain

10 This article focuses on the authorization for the cultivation of GMOs in the EU. The authorization for GMOs as or in food and food products, feed and feed products as well as the use of GMOs for any other purpose will not be touched upon.

larvae widely across the EU for more than 20 years (ibid.). It went on to state that "the development of resistance in injurious target pests wil be delayed by the rigorous adoption of a comprehensive resistance management strategy" (ibid.), in particular stringent monitoring rules. Although a risk concerning cultivation of MON810 was identified, the SCP stated that this risk would be sufficiently mitigated (ibid.). Shortly afterwards, MON810 was authorized throughout the EU on the basis of this SCP report. This shows that the scientific body, i.e. the SCP, was trusted enough to convince the policy-makers of their recommendation. Hence, the SCP can be seen as the *de facto* decision maker in this particular process.

5.1.1.2 Renewal of the Authorizatio n for MON810

After Regulation 1829/2003/EC had entered into force, MON810 was duly notified to the Commission by Monsanto on 12 July 2004 as existing products in accordance with Art.8(1) and Art.20(1) of Regulation 1829/2003/EC (European Commission, 2011, a). Hence, in 2007 Monsanto Europe applied for renewal of authorization for the use of MON810 for food and feed products, import and processing, as well as for the cultivation of MON810 in the EU under Regulation 1829/2003/EC (Monsanto, 2007).

Currently, the renewal of authorization for cultivation and all other uses of MON810 is still pending (European Commission, 2011, b). Although the original authorization expired in 2008, according to Art.23(4) of Regulation 1829/2003/EC, MON810 may still be placed on the market, and thereby also cultivated, until an official decision in the matter has been taken. EFSA has already given an opinion on the case at hand (EFSA, 2009) and has forwarded it to the Commission, the MS and the applicant in conformity with Art.18(6) Regulation 1829/2003/EC, but still no decision has been taken.

EFSA's scientific opinion describes MON810 to be "as safe as its conventional counterpart with respect to potential effects on human and animal health" (EFSA, 2009, p.56). Furthermore, EFSA stressed the fact that the *Cry1A(b)* had been extensively assessed in previous opinions of the EFSA GMO Panel and that it has continuously been found to be safe (p.23). In its opinion, EFSA thoroughly responds to concerns regarding the adverse effects MON810 could have on various non-target organisms and repeatedly comes to the conclusion that this GM crop is unlikely to have adverse effects on various non-target organisms (pp.2748). However, in the case of non-targeted lepidopteran larvae EFSA admitted that more data would be required to rule out uncertainties which are inherent in any ecological modeling exercise (p.37). It continued to advise to accompany the adoption of the cultivation of MON810 by stringent management measures. Regarding the development of target organism resistance, EFSA estimated that "no significant risk

has been identified in the environmental risk assessment with the exception of resistance evolution in lepidopteran target pests" (p.50). EFSA therefore recommended that the development of resistance in lepidopteran target pests to be persistently monitored so that potential changes are detected promptly (p.54).

5.1.1.3 National Bans and Safeguard Clauses

Once a GMO product has been authorized under the appropriate legislation, it may circulate freely within the EU without MS being allowed to hinder it. This is guaranteed by Art.22 Directive 2001/18/EC. Nonetheless, Art.23(1) Directive 2001/18 provides MS with a safeguard clause, entailing the possibility to temporarily restrict the use of certain already authorized GM products if there are justifiable reasons to believe that they constitute a risk to human health or to the environment. While the emergency clause under Art.34 of Regulation 1829/2003/EC allows for legitimate factors *other than science* to be taken into account, this does not apply to the safeguard clause under Directive 2001/18/EC. When invoking this article, only new or additional *scientific* information made available after the authorization may be considered.

Until now, several MS have invoked the safeguard clause in order to restrict or prohibit the cultivation of GMOs. Currently MON810 is banned from being cultivated in Austria, Greece, Hungary, France, Luxembourg, Germany and Bulgaria. Several MS base their justification to invoke the safeguard clause on claims that MON810 negatively affects nontarget species and facilitates the development of resistance in target species. Yet, the SCP and later EFSA re- emphasized that there are no scientific reasons to think that MON810 would adversely affect health or the environment (EFSA, 2006, p.9). Furthermore, EFSA emphasized several times that the scientific evidence presented by the MS could not be considered as new or consisting of additional information. Despite the Commission's request to lift these national bans, many of them still remain in place due to the lack of support in the Council. Through this analysis, it becomes clear that the thresholds for taking precautionary measures are set differently by the MS and EFSA, which in turn leads to MS questioning the risk assessments made by EFSA and reduces trust in this scientific body by the MS.

Not only on EU level did these national bans cause controversies, but also on the WTO level. In 2003 the US, Canada and Argentina started proceedings against a number of MS as well as the Commission, criticizing not only the alleged moratorium[11] on GMO

11 "[A] general de facto moratorium on approvals was in effect in the European Communities between June 1999 and August 2003" (WTO Report, 2006, p.760). For more information see Prevost, D. (2007). Opening Pandora's Box: The Panel's Findings in the EC-Biotech Products Dispute. *Legal Issues of Economic Integration, 34*(1), 67101.

authorizations but also the national bans by several MS on specific GM products (WTO, 2006, para.2.1). The WTO Panel came to the conclusion that the national safeguard measures did not comply with the SPS Agreement. It was assessed that these measures fell outside the scope of Art.5.7 of the agreement, as this provision can only be invoked if the relevant scientific evidence is insufficient. However, the opinions issued by the SCP and EFSA were recognized as being valid risk assessments for the purpose of the WTO and stated that scientific evidence was sufficient. Nevertheless, the scientific evidence presented by the MS to justify their safeguard measures could not be qualified as a valid risk assessment as required under Art.5.1 of the SPS Agreement.[12] Therefore, the WTO Panel came to the conclusion that the national safeguard measures were not in compliance with Art.5.1 and that the MS in question breached their obligations of the agreement.

Besides political and legal consequences, safeguard clauses also have economic implications for the applicant in question as was expressed by Monsato, Belgium (Monsanto, 2011). First, producers of GM seeds loose the markets in those MS that decide to ban cultivation. Secondly, the invocation of safeguard clauses based on scientific uncertainty also impacts the sales in third countries by giving the product a negative connotation. These issues clearly point towards the necessity of consistent policy making for GMOs, which is emphasized by the following case study on Bt11.

5.1.2 Bt11

In 2003 Syngenta applied for authorization for cultivation of Bt11 with the French Competent Authority in France, which duly forwarded its favorable opinion to the Commission on 16 June 2003 (EFSA, 2005, p.4) and the other MS. Questions and concerns raised by the other MS revolved around the increase in resistance in target pests as well as the negative effects of the toxin on non-target species (EFSA, 2005, pp.5-23). The Commission hence asked EFSA for its scientific opinion, which was published on 20 April 2005 and addressed all concerns forwarded by the MS. The possible development of resistance to Bt-toxin in target pests was identified as a possible but low risk and EFSA supported the monitoring plan[13] to control these unwanted effects. Furthermore, "appropriate risk management strategies" (EFSA, 2005, p.24) were suggested to be taken in order to minimize effects on non-target insects, although EFSA also stated that the actual possibility of such effect was "foreseen to be very low" (EFSA, 2005, p.20). Overal the EFSA GMO Panel concluded that "there is no evidence to

12 The requirements for a valid risk assessment are laid out in paragraph 4 of Annex A of the SPS Agreement.

13 Such monitoring plans are required according to Art.20 (1) of Directive 2001/18/EC.

indicate that placing of maize line Bt11 and derived products on the market is likely to cause adverse effects on human or animal health or the environment" (EFSA, 2005, p.24).

The scientific opinion depicts the development of resistance in target pests as possible, but still concludes that cultivation of Bt11 does not endanger human and animal health or the environment. The low prioritization of this possible effect suggests an implicit cost-benefit analysis, which prioritizes the benefits of cultivation over the possible adverse long term effects of Bt-toxins. Thus, (non-)precautionary rationales also have a real impact on the risk analysis and a cost-benefit analysis can lead to the downgrading of a certain risk and can therefore "itself determine the outcome of a risk assessment" (Motaal, 2005, p.495).

After EFSA's scientific opinion, the authorization procedure for Bt11 took a rather unusual turn. Instead of issuing an opinion, the Commission held a technical meeting with MS and EFSA representatives to "discuss the notifications pending under Directive 2001/18/EC (EC, 2001) and including cultivation purposes" (EFSA, 2006, p.1). It enabled the MS to further articulate their concerns about the cultivation of GMOs like Bt11 and also to express their discontent about the EFSA report. As a result, EFSA was requested to further elaborate on certain issues, particularly on the unanticipated effect of the Bt-toxin on non-target lepidopteran species and on appropriate monitoring plans.

Subsequently, EFSA published the requested Annex to its scientific opinion in which it reaffirmed its position towards the effect of Bt11 on health and the environment (EFSA, 2006, p.7). Thus, during a time span of two years the GMO Panel of EFSA had confirmed the safety of Bt11 for cultivation twice.

The technical meeting revealed that MS were apparently not willing to fully trust the first risk assessment carried out by EFSA and demanded further elaborations. Arguably, the issues that were chosen by the MS for further assessment were those which were handled with a relatively high level of precaution on the respective national levels. However, the GMO Panel's Annex possibly bears witness that EFSA did not recognize the apparent gap between its own precautionary threshold and the one desired by MS and therefore did not to move away from its previous assessment.

5.1.2.1 Parallel Developme nts

Reviewing the past authorization procedures of GMOs in the EU, the Commission published an Action Plan in 2006. The idea behind this was to introduce "practical improvements [that] could be made to the system to improve the scientific consistency and transparency for Decisions on GMOs and develop consensus between al interested parties" (European Commission, 2006). Thereupon, EFSA held a Scientific Colloquium,

concluding that more information was necessary to generate guidelines on how to assess potential risks of GMOs on non-target organisms. EFSA thus started a project titled *Cry proteins and their expression in micro organisms and genetically modified plants* (European Commission, 2007, recital 12). This project was meant "to provide EFSA with a review of all appropriate scientific data on Bt-proteins that are relevant for the risk assessment of GM plants expressing such proteins" (ibid.). Most importantly, however, the assignment was also supposed to include an overview of areas that have not been researched yet, thereby guiding and coordinating future research. Although this first serious attempt to base the use of the PP on a fully developed scientific review, including minority and majority decisions would have helped to combat the apparent lack of trust among MS in EFSA's scientific assessments, the project was never completed (EFSA, 2011, a).

5.1.2.2 The Commissio n Proposal to ban Cultivatio n of Bt11

In 2007 the Commission drafted a Decision to ban the cultivation of Bt11. It featured the findings of eleven scientific studies emphasizing the scientific uncertainty surrounding the effects of Bt11 on non-target organisms (European Commission, 2007, recital 14) and concluded that it was evidently still possible to identify uncertainty concerning the cultivation of Bt11. The risks involved were said to have potentially far-reaching and even irreversible consequences and would render management measures as proposed by EFSA ineffective and inappropriate (recital 21). In the draft explicitly the Commission argues that considering the level of uncertainty still surrounding potential effects on non-target lepidopteran insects, it is impossible to approve the cultivation of Bt11 without disregarding the PP. This argument implies that the threshold of precaution applied by EFSA was clearly not high enough to satisfy apprehensions of opposing MS. Nevertheless, this ban was never adopted.

After the Draft Decision had been published, EFSA was requested to assess the eleven scientific studies and thereby include minority scientific views. In October 2008 EFSA published its opinion on the 'new' scientific evidence, which disagrees with the Commission's assessment that these studies constituted "serious indications" (recital 21) of Bt11's high risk of adverse effects on non-target organisms. The scientific evidence referred to by the Commission in its Draft Decision is described as "not [providing] new information that would change previous environmental risk assessments" (EFSA, 2008, p.21). EFSA therefore "reaffirm[ed] its previous conclusions on the environmental safety of maize Bt11" (ibid.). This last assessment emphasizes the gravity of the deadlock of diverging risk thresholds of precaution in the authorization procedure.

Although compared to MON810 a more open strategy of communication and multiple risk assessments was employed with Bt11, the authorization has still not been completed.

A higher degree of openness, including back and forth discussion about possible dangers of cultivation of Bt11 between the MS and EFSA, did not lead to an agreement between the two. Moreover, not all MS were willing to support a complete ban for cultivation either, as has been shown by the failure of the Regulatory Committee to adopt an opinion on the Draft Decision. Although a deadlock could be interpreted as a temporarily satisfying situation for MS that oppose the cultivation of Bt11, considering the WTO's stance towards such delays, the situation is unlikely to stay unresolved.

5.2 The Problem Inherent to the Authorization Procedure of GMOs in the EU

The cases studies were initially chosen due to the seemingly inconsistent and arbitrary application of the PP resulting in the different outcomes of both cases in spite of the striking similarities. However, it soon appeared that the reason for inconsistent policy outcomes of the authorization processes of MON810 and Bt11 is not to be found in an inherent arbitrariness of the PP. Nor was it an inconsistent application of the PP by the same actors that has led to the approval of cultivation in one case, and a deadlock situation in the other. Moreover, the slightly diverging, yet still very similar legal frameworks for the initial authorization of both products can also not solely account for the regulatory incoherence, since both frameworks to some degree provide room for precautionary action.[14]

Rather, the technical meeting and the subsequent second request to EFSA suggest that the authorization procedure of Bt11 depicts an alternative strategy employed by the MS to handle the situation of cultivation of GMOs. Invoking safeguard clauses had proven to be an ineffective way to prevent cultivation due to the rejection by the Commission, based on the lack of new scientific evidence provided by the respective MS and their failure to comply with WTO rules. Therefore, it is possible to argue that for Bt11, those MS that opposed the idea of cultivating the GMO tried to opt for a more open and communicative risk assessment procedure. Altogether, by improving the communication process between all decision-makers, a less linear application of the PP was used. Admittedly, the intention of the second request to EFSA might have been a genuine desire by the MS to include all available scientific information and possibly to create consensus. Nonetheless, it already suggested a different prioritization of risks used by the MS and EFSA, as expressed by the MS' request to EFSA to elaborate on issues that already had been assessed. Still, this strategy of back and forth communication proved not to lead to a decision acceptable for all actors, either. Since both strategies have failed to deliver adequate regulatory results,

14 Directive 90/220/EEC only demands that attention is given to "precautions related to the safe use of the product" (Art.12), whereas Directive 2001/18/EC explicitly mentions the PP.

the Commission currently plans to amend Directive 2001/18/EC[15] leaving more leeway to MS in the area of GMO cultivation.[16]

The analysis of both risk assessments therefore suggests that the main problem of coherent authorization can be found in a difference in thresholds of precaution applied by the opposing MS and EFSA.[17] The authorization procedure for GMOs (in particular the risk assessment) has to shoulder the pressure of reconciling up to 27 different societal perceptions of risk and appropriate levels of precaution, and to allow the decision to be incorporated into 27 different national legal cultures. In both authorization procedures the MS and EFSA agreed on the possibility of such undesired effects of non-target insects, yet their evaluation differed. This constitutes the actual problem.

As a result, the authorization procedures of GMOs in the EU have to be considered rather incoherent and unpredictable. This in itself is fairly undesirable, as it defeats the purpose of regulation on a European level. Moreover though, applicants are likely to be unsatisfied not only with the diverging policy-outcomes, but also with the procedural unpredictability of the current system, which makes it difficult to organize and adjust investments and R&D (Monsanto, 2011). Therefore, it is easy to see that there is room for improvement in the field of GMO authorization.

6. Scenarios

When developing scenarios, it is important to emphasize that there is 'no correct scenario definition or approach', but that they can be applied in a rather flexible manner, tailored to the needs of the researcher (van Notten et al, 2003, p.424). In fact, scenarios and future studies are usually a mix of several methodologies and types of scenarios (Robinson, 2003). Due to this flexibility, the approach makes it possible to develop two different scenarios, one extrapolating from current developments (Commission scenario) and one addressing the problem identified in the case studies (FRAD scenario). By doing this, this article intends, on the one hand, to illustrate the likely consequences of current developments,

15 Mr. Koehler from the BMELV suggested that the Commission currently stalls the authorization procedures to wait for these reforms.

16 This proposal by the Commission is discussed in the following chapter.

17 Mr. Kohler from the BMELV explained this difference in precaution as partly stemming from backgrounds of the experts working in the EFSA Panel as scientists working with GMOs for several years are more comfortable with the idea of GMOs and also more convinced of the safety.

and on the other, to depict how a working procedural PP can be incorporated into the regulatory process for GMOs in the EU. The techniques that will be applied in the following are qualitative, as this allows a more thorough examination of possible consequences, perceptions of the PP, and Member States reactions.

Despite all suggestions about probabilities, one must always keep in mind that scenarios are "not a tool to predict the future", but a method that provides actors with insights into possible future consequences of existing uncertainties (Fox et al, 2011, p.32), which is why they can be of high relevance for policy makers, stakeholders, policy analysts and other interested parties (ibid.).

6.1 Commission Scenario

Considering the above-mentioned case studies, one can conclude that certain MS are not willing to cultivate GMOs on their territory and have in the past used different strategies in order to resist cultivation, none of which have been proven to be very effective in the long run. The MON810 case has shown that safeguard clauses cannot be seen as a suitable tool to permanently ban the cultivation of GMOs. The Commission has repeatedly requested the respective countries to lift these bans and also the WTO Dispute Panel has declared these national bans illegal since they cannot be justified by valid risk assessments (WTO, 2006). Also, the strategy applied in the authorization process of Bt11 does not offer a worthy alternative, since stalling the process altogether can also be seen as a violation of WTO laws, as it leads to undue delays in the authorization procedure, which was highlighted by the WTO Dispute Panel in the EC Biotech case (WTO, 2006). Looking at it from the EU level, one must also highlight that if a decision- making procedure loses its capability to produce effective decisions, it is likely to be flawed.

As a result of growing pressures by certain MS[18] the Commission submitted a proposal for a regulation to the Council, which is to amend Directive 2001/18/EC.[19] This new provision gives MS the freedom to restrict or even prohibit the cultivation of GMOs on their territory on grounds other than health or the environment. From the point of view of opposing MS, the proposed amendment seems to be quite an attractive solution to the current GMO cultivation issue, as it would allow decisions concerning GMO cultivation to be taken at national or even regional level.

Such decisions could consider certain particularities and different perceptions on

18 After the Council rejected the Commission's proposal requesting Austria and Hungary to lift their bans in March 2003, 13 other MS requested the Commission to draft a legislative proposal, granting more freedom to Member States when it comes to the cultivation of GM crops in the EU.

19 Proposal to insert Art.26(b) (Cultivation) of Directive 2001/18/EC as proposed in COM (2010) 375 final.

the precautionary thresholds of that area. Moreover, justifications for bans need no longer to be scientific, thus implying more flexibility for the MS in the matter (European Commission, 2010, p.3). With this new provision, the Commission hopes to decrease the MS' use of the safeguard clauses, speed up procedures and reduce the institutional burdens on the Commission as well as on EFSA (p.4). These burdens arise due to the consistent objections by MS to opinions and reports of both institutions. Moreover, the Commission is convinced that this new provision will benefit affected stakeholders by providing more clarity about cultivation of GMOs and by rendering the decision-making process more predictable (ibid.). In short, the proposed amendment to Directive 2001/18/EC seems very attractive in the short run since it appears to cater to the interests of all parties involved, seemingly addresses the issue of diverging thresholds, and also because its effect is quite easily achievable. However, when examining the proposed amendment more closely, one will discover that in the end the newly won freedom is in fact rather limited as MS will have to adhere to EU, as well as to WTO law.

First and foremost, the possibility to invoke safeguard clauses based on the proposed amendment is still not likely to comply with WTO law.[20] Second, the rationale behind this approach is questionable. Instead of improving the enforcement of current EU law, the Commission now seems to change the law which was violated, thereby rewarding those that breached it in the first place (BMELV, 2011). Thirdly, the measure does not address the initial criticism of the PP, as it does not create procedural coherence or certitude for all involved stakeholders, regarding the principle's procedural application. In fact, shifting the application back to the MS level eradicates all efficiency gains which constituted the initial reason for a European application procedure, thereby constituting a step backwards in the process of European integration. Such a reversal of the European integration process must be seen with caution, not only due to possible implications for the internal market, but also with regards to growing Euro-skepticism in many MS. Consequently, it is intelligible to develop an alternative scenario which seeks to overcome the procedural problems of the PP on a European level.

6.2 Full Risk Assessment Dossier (FRAD) Scenario

The case studies above have revealed that the issue at hand mainly lies with the different threshold levels of precaution inherent in the different risk perceptions applied in the procedure by the MS and EFSA. In order to make the authorization procedure of GMOs in

20 A detailed discussion of compliance with WTO-law when invoking safeguard clauses solely against cultivation unfortunately goes beyond the scope of this paper.

the EU more coherent and effective, while still ensuring flexibility for MS, it is necessary to approximate the different threshold levels of precaution. Naturally, this common threshold level should not equal the one of the MS with the highest threshold, since this could easily lead to a zero-risk strategy which in turn could result in overregulation. Rather, the MS and EFSA need to meet half way; EFSA has to acknowledge that certain MS have a higher level of precaution, whereas the MS have to rekindle their trust in EFSA's risk assessments. A higher level of trust in EFSA would mean that MS would more easily approve of a risk assessment with a lower precautionary threshold than their initial national threshold.

To increase trust while maintaining the current science-based authorization system for GMOs on the European level, this scenario proposes the creation of mandatory Full Risk Assessment Dossiers (FRADs)[21] by EFSA, on which every European and national precautionary measure has to be based. Although the EFSA reports should continue to contain non-binding recommendations, there is a need for more transparency, as well as traceability of its reasoning. Hence, a scientific opinion by EFSA should provide all the possible interpretations of scientific data available, including minority scientific views to increase its credibility. Most importantly, EFSA has to make all (non-)applications of the PP very clear, such as whether it took into account a cost-benefit analysis or proportionality requirements in their evaluation of the product's overal risk. In short, al implicit applications of precaution need to be made explicit.

A FRAD could be characterized as the centralization of scientific knowledge, a review of all relevant scientific research and related risk assessments brought together by EFSA. Such a review would include a clear identification of areas of uncertainty, which have not been researched yet. Any stakeholder could forward their scientific findings to EFSA, which would in turn provide a comprehensive overview of the scientific state of affairs. In order to ensure compliance with WTO law, only risk assessments in conformity with Art.5(1) SPS Agreement will be accepted by EFSA for this compilation. During the process of data collection, EFSA must refrain from any explicit or implicit (non-)application of precaution. This phase should only focus on the scientific quality of the data that is to be included in the FRAD. Moreover, the FRAD is to be updated annually as to ensure the actuality of the review.

The possibility of invoking a safeguard clause should nevertheless still be available to cater to the needs of MS with unusual high precautionary thresholds and to provide fewer incentives for MS to block the whole authorization process. When invoking a safeguard clause, the respective MS would always have to justify its measure based on one of the

21 The idea of the FRAD is built on the uncompleted EFSA project *Cry proteins and their expression in microorganisms and genetically modified plants* mentioned in Chapter 5.2.2 of this article.

scientific risk assessments contained in the FRAD. By doing so, non-compliance with WTO law would be avoided and minority as well as majority science could be taken into account, as long as there is a valid risk assessment. Since the FRAD would be updated regularly, the question whether a piece of scientific information is 'new' or 'additional' would not arise, as the MS could rely on the FRAD. Therefore, a FRAD means to play a game with open hands, thereby achieving greater certainty for MS and other stakeholders concerning the process of authorization. Moreover, it would prevent the abuse of safeguard clauses.

It is needless to say that different versions of the PP as proposed by Wiener and Rogers will continue to exist. Particularly in situations where the opinions on precaution are too divergent, it will be more difficult to find a compromise on a common threshold level of precaution. However, this problem is inherent in the multi-level governance structure of the EU which always necessitates a political dimension to the decision-making process (BMELV, 2011). By introducing the compulsory use of a FRAD, a certain degree of certainty would be established which in turn would reestablish trust in EFSA. This would allow for an approximation of levels of precautionary thresholds with the possibility for MS with high thresholds to nevertheless legally invoke temporary safeguard clauses. Through the codification of the handling of scientific knowledge in the EU an appropriate application of precautionary measures will be ensured.

7. Conclusion

Recalling the initial starting point of this case study, namely the question as to why in two cases of similar scientific uncertainty the policy outcomes varied considerably, this paper has to conclude that any explanation has to go beyond criticizing an inherent incoherence or arbitrariness of the PP. It has been shown that the immediate reasons for the diverging authorization processes of the two GMOs in question are to be found in how the PP has been incorporated into the procedural framework of the EU and the strategies applied by some MS in order to achieve their objective of resisting cultivation of GMOs. After the first strategy of employing safeguard clauses for MON810 had been unsuccessful, concerned MS reacted by employing a different strategy in the case of Bt11, which in the end led to a standstill of the decision-making process altogether. These strategies were motivated by an underlying rationale of the diverging thresholds of precaution employed by MS, the Commission and EFSA respectively. Therefore, the inconsistent policy outcomes of the two authorization procedures can be explained by exactly this difference of precaution employed by the actors.

Within the current EU framework governing the authorization for cultivation of GMOs it was not possible to find a compromise between the involved stakeholders.

What lessons can be drawn from this case study, regarding the regulation of GMOs in the EU? First and foremost, not the PP itself, but rather diverging thresholds for its use have caused undesirable regulatory results. Hence, it is questionable whether the Commission's proposal to disintegrate the decision-making process for the cultivation of GMOs is the only and best solution to this problem. It would only circumvent the issue at hand, instead of solving it. Moreover this would mean to sacrifice the benefits of regulation on a European level and possibly distort the internal market. Furthermore certain health and environmental risks connected to the use of GMOs transcend borders and therefore demand EU-wide solutions. Therefore, this paper has brought forward an alternative solution which keeps regulation on a European level, without compromising MS' capabilities of setting their own risk-thresholds. By requiring EFSA to develop FRADs, and by creating a process that is open to all stakeholders, the use of the PP can become more predictable and render the decision making process more effective. This can only be achieved by enhancing MS' trust in EFSA, as wel as by a convergence of risk-thresholds. Furthermore, the review of all available scientific data would be guarded by strict procedural rules, making it easier for future authorizations to adhere to timelines.

In addition, recal ing the more general criticism of the PP as an 'arbitrary', 'paralyzing', or 'non-science based' principle, one has to conclude that these features *can* be side-effects of the PP, yet the reasons for such results are to be found in the procedural application of the principle. Particularly in complex multi-actor, multi-level-governance frameworks such as the EU, it is very challenging to design a procedure that can reconcile all different perceptions of risk. Moreover, designing a procedural PP for the EU is especially difficult because it has to conform not only to national and European, but also to the international WTO legal framework.

Therefore, it is important for subsequent research to further develop a 'procedural PP', since traditional versions and interpretations of the PP can help explain the principle's shortcomings, yet provide little direction on how to solve its problems. The 'tool-box' provided by this paper addresses this deficit by providing a methodological framework that allows the researcher to analyze the PP in a procedural realm and address its flaws by designing practical changes which are to be integrated into the legal framework of a regulatory regime.

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Risk under construction:

The German discourse on the ban of MON810

Carolin Ifländer, Felix Kartte, Sonja Koehler, and Juliane Reschke

Table of Contents

1. Setting the Scene

Food crises ranging from BSE to EHEC have time and again demonstrated that uncertain risks in the area of food safety constitute one of the main societal challenges we are currently facing. Their nature as "possible, new, imaginable hazards, with which society has no or limited experience" (van Asselt and Vos, 2008) leads to situations in which traditional means of science prove to be inadequate for drawing suitable conclusions informing how the uncertain risk is to be handled. This challenge is particularly visible in the regulation of genetically modified organisms (GMOs): they have been characterized as an uncertain risk and pose questions related to socio- political, economic and cultural considerations (Ansell and Vogel, 2006; van Asselt and Vos, 2008).

How GMOs are regulated is a question with national as well as international implications. National rules interact with EU law and are embedded in the multilateral WTO/GATT framework. In this paper we will take a closer look at the implications of the EU model after its institutional re-organisation. This re-organisation was necessitated by several food scares and crises which highlighted the inadequacies of the ad-hoc approach to food safety regulation and a focus on economic rationality of the former system (Chalmers, 2003; Vos, 2004; Vos and Wendler, 2006). The most influential novelty of the EU approach to risk regulation was the institutional separation between risk assessment and risk management. This bi-institutional model was supposed to provide "independent" risk assessment in order to restore public trust into the system of food regulation (Dreyer & Renn 2010, p. 4). Accordingly, science should "no longer be seen to be policy making" and therefore be deprived of its exclusive influence on risk management (Löfstedt, 2005, p.xx). This institutional rationale can be said to reflect the ideas of post-normal science (PNS) (Ravetz, 2006). The paradigm is associated with the recognition that science is not and cannot be value-free - even less so in situations of scientific uncertainty. Instead of treating science as a realm *above* society, it should be understood as a product of social context. PNS provides us with a valuable lens to understand the changing role of science within governance and society at large (cf. De Marchi and Ravetz, 1999; Wesselink and Hoppe, 2010).

Within this new framework, the European Food Safety Authority's (EFSA) GMO panel is entrusted with the role of risk assessor. It assesses and evaluates the risks posed by GMOs and GM product and forwards its opinion to the risk manager. The function of risk management is attributed to the European Commission and the Member States. Other important actors involve the risk producer and risk protesters. They provide input to the regulatory process, but do not have an instutionalised role in the process (van Asselt & Vos, 2008; Ravetz, 2001).

Notwithstanding the removal of science from the decision-making core and the institutionalised recognition thereof, risk managers still expose a tendency to justify decisions exclusively on the basis of scientific findings. This has been the case with regard to the ban of GM maize MON810 in Germany, which was announced in 2009. This GM variant is a Bt-insect- resistance trait. The German authorities presented the measure as a scientific imperative and made no reference to the social, economic and cultural dimensions that influenced the decision. In this way, the impression has been created that the decision was based on certainty with regards to the potential consequences of MON810. This is noteworthy, since the expert assessment of MON810 was marked by uncertainty concerning potential hazards. This apparent contradiction hints at the fact that a perceived risk is irreducible to its scientific evaluation, but rather emerges in wider social processes of communication about the risk (Kasperson et al., 1988; Johnson, 2008). In order to be able to properly assess a risk decision we should look beyond the technical analysis and take into account the impact of relevant social actors on characterizing the risk. This is a challenging task in the case of the German ban of MON810, since multiple actors were involved in the respective public debate, ranging from risk producer to the media, risk contesters and risk managers.

In an environment in which science is no longer the ultimate benchmark, the Social Amplification of Risk Framework (SARF) constitutes a helpful tool to account for the collective effect of multiple actors on *risk construction*. The process of risk communication is conceived as the transfer of signals between information sources (e.g. the risk assessors) transmitters (e.g. the media, interest groups) and receivers (e.g. industry) (Renn, 2008, p. 376; Kasperson et al, 1988). In this way, it is able to yield explanations of why the social characterisation often deviated strongly from the scientific assessment of risk. Accordingly, technical assessments are restricted to the dimensions of probability and magnitude, while society has a more comprehensive concept of risk that incorporates social, economic and cultural values. When technical assessments come to interact with these values, risks are therefore either amplified or attenuated. The proponents of SARF, however, regard this as a positive effect as it leads to a fuller determination of the risk (Kasperson et al, 1988). A cluster of meaningful signals pertaining to the same topic is called a message. By comparing the properties of messages about a risk, then, one can learn how actors selectively interpret facts and anticipate consequences (Renn, 2008, p. 376).

Although SARF has been criticized for being too mechanistic in terms of separation between messenger and message (Renn, 2008), it can be countered that the two are not understood as distinct from each other, since each message is shaped according to specific values and norms of the actor in question. Consequently, the framework allows

us to scrutinize the influence of collective dynamics on the definition of social risk and simultaneously to identify the effect of singular actors on this process.

However, we would like to modify the traditional SARF approach for our analysis as it privileges the technical assessment of risk over the social assessment when talking about risk amplification and attenuation respectively. In areas of certain risks, for example the danger inherent in smoking, the prioritization of science over the opinion of the tobacco lobby might be adequate. Yet, in areas of *uncertain* risks, there is no reason to prioritize scientific definitions over social ones, therefore, we deem it more appropriate to speak of *risk construction,* rather than amplification and attenuation. This change of terms enables us to understand risk construction as a continuous process in which scientific and social actors participate on equal footing.

On the basis of this conceptual understanding, we will analyze the discursive process of risk construction which informed the German ban of MON810. Although this special GM-maize variant is authorized on EU level,[1] its cultivation has been banned by several Member States by invoking the safeguard clause laid down in EU law. In comparison to other Member States,[2] Germany has a rather inconsistent anti-GMO policy. This can be said, since the ban of MON810[3] marks a contrast with the authorization of genetically modified sugar beet, potatoes, spring wheat and other variants of maize in 2011.[4] Because of this inconsistency and the controversies involved, we consider the German case a particularly interesting example.

The ban of MON810 in Germany followed a debate which involved multiple actors with conflicting risk representations. While the risk producer, Monsanto, claims that the product is safe, the responsible German Minister of Consumer Protection justified the ban by indicating that MON810 poses a risk to the environment. Furthermore, the involved risk protesters stressed that scientific experts established uncertainty about the safety of the MON810. Although arriving at contradictory risk representations, all actors based their accounts on scientific insights. Consequently, the situation is marked by the uncertainty paradox: although MON810 poses an uncertain risk – which implies that certainty cannot be established through scientific assessment – the different actors turn to science in the search for conclusive answers (van Asselt and Vos, 2006, 2008).

In order to be able to assess the implications of the ban, we will analyze the discursive process of risk construction in relation to MON810 in order to reveal shortcomings of the current model and practicalities of risk regulation. Our understanding of SARF will help us to identify discursive patterns and their implications for risk construction. Moreover, it can guide us in discovering problems and possible improvements of risk communication in the area of EU food safety.

After introducing the EU's legal framework in which GMOs in general and MON810 in particular are regulated, we present a critical discourse analysis in which we follow the discourse- historical approach. The first step will be to conduct a first-order critique in order to unravel rhetoric and discursive patterns of the different actors which will reveal the influence of the different actors on risk construction. This will be followed by a second-order critique in which our findings will be evaluated in the light of current debates on risk governance. After providing some recommendations based on ongoing scholarly debates, the last part of the paper will provide summarizing remarks.

2. GMO Regulation

This section will commence with a brief overview of the current EU regulation of GMOs within the framework of food safety regulation before examining how MON810 is governed on the EU level. Following, it will be explained how the German ban is situated in the legal framework.

The current EU framework for food regulation is laid down in Regulation 178/2002 (hereinafter General Food Law or GFL) and is guided by two main principles: the promotion of the internal market and the protection of public health and safety.[5] The system set out by the GFL incorporates the separation between risk management and risk assessment as explained above.

The Commission and the Member States are responsible for risk management while EFSA provides scientific risk assessments.[6] This separation of tasks is aimed at insulating science from value-laden discussions about how to regulate risks. "Scientific knowledge is authoritative, but not exclusively so" (Skogstad, 2001, p.490), because managers may also take other 'legitimate' factors such as social considerations, the precautionary principle and/or international standards into account when judging the acceptability or tolerability of risks.[7]

In the case of GMOs, Directive 90/220 used to regulate the authorization procedure, but was later amended by Directive 2001/18 and Regulation 1829/2003.[8] The current framework provides for authorization by the Commission based on a risk assessment made by EFSA. Authorizations are granted for specified time periods and can be renewed upon request by the producer. The Member States also play an important role in this process, as applications for authorization are submitted to competent national authorities first and Member States are consulted[9] on the application and can eventually invoke a safeguard clause to ban a GMO or GM product.[10] We can therefore observe that the EU's institutional framework concerning GMO regulation places science *within* and not *above* society and thereby removed science from the decision-making core.

3. Regulating MON810

When Monsanto applied for authorization of MON810 at the competent French authority in 1995, Directive 90/220 still applied and determined the regulatory procedure for GMO cultivation. The French authority therefore examined whether Monsanto's application complied with Directive 90/220 and then forwarded its favorable opinion to the Commission. The Commission drafted its consent and informed the other Member States' authorities. However, objections were raised and the Commission had to refer the case to a standing committee - the Scientific Committee for Plants (SCP, which can be regarded as the predecessor of EFSA) in order to obtain a scientific opinion. The SCP was composed of Member State representatives and chaired by the Commission, so in this case which took place before the institutional reform of the EU's food safety regime, political decision-making and science were not separated from each other. In February 1998, the SCP came to the conclusion that there was no reason to believe that placing MON810 on the market would entail any adverse effects on human health or the environment. Following this opinion, the Commission adopted its Decision 98/294 which envisaged the authorization of MON810. On the basis of this decision, the French Agricultural Ministry granted the authorization for the deliberate release of MON810 into the environment in 1998.[11]

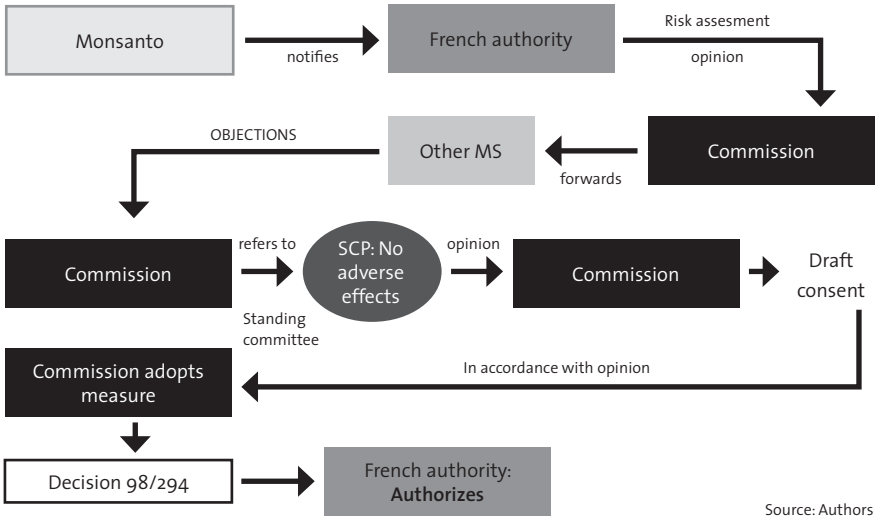


Figure 1 Procedure according to Directive 90/220 - MON810; 1998

Following the revision of the EU's regulatory framework for GMOs in 2001 and 2003, MON810 and the products originating from or containing it were notified as already existing products[12] and are therefore now authorized in the EU under Regulation 1829/2003. Monsanto duly filed for renewal of the authorization in 2004. This procedure is still ongoing which means that, in principle, MON810 may be cultivated in the EU.

However, several Member States[13] have installed safeguard measures which limit or ban the maize variant. They were able to do so due to safeguard measures which were provided in the old as well as the new GMO regime. The safeguard measures may be applied if a Member State has justifiable scientific reasons to consider that an already authorized GMO poses a risk to human health or the environment.[14] Germany is one of the countries which have such a measure in place.

In principle, the authorization of MON810 which was granted by the French authority in 1998 is effective in Germany[15] and the GMO may therefore be cultivated and placed on the market until the process of re-authorization is completed. However, in August 2007, Germany invoked the EU law safeguard clause for the first time and temporarily suspended the authorization of MON810 as it ordered Monsanto to enact and comply with a monitoring plan. The German authorities argued that their decision was aimed at ensuring a high level of precaution until a decision about the re-authorization was reached. This suspension was lifted again in autumn 2007 when Monsanto presented a monitoring plan which was in accordance with EU law (BVL, n.d.). In April 2009, Germany invoked the safeguard provisions[16] again, claiming that scientific studies provided conclusive evidence of negative effects of MON810. This time, it enacted a *ban on the cultivation* of MON810, which has the effect that the 1998 authorization is suspended until either Commission or Council repeal the safeguard measure or when the re-authorization becomes definite. Monsanto challenged the ban in front of two courts. The lower Court (Verwaltungsgericht Lüneburg) decided that the ban was in conformity with the German law on GMOs and the higher Court (Oberverwaltungsgericht Braunschweig) also held that it was justified. However, the case is not fully decided yet as the proceedings were suspended in order to give Monsanto and the German authority the possibility to reach an agreement concerning the ban and its consequences outside the court room (VG Braunschweig, 2009; Redaktion Beck- Aktuell, 2009). If the parties cannot find an agreement themselves, the Verwaltungsgericht Lüneburg will have the final say and it is, given the two previous judgments, likely that it is ready to uphold the ban.

This section provided a short overview of how GMOs in general, and MON810 specifically, are regulated at the EU level and in Germany. It already pointed towards the fact that there is much debate around the risk MON810 poses to the environment

and human health. The German authorities invoked a safeguard clause on the basis of scientific findings, which was contested by Monsanto. The following section will provide more insights into this debate by examining how different actors communicated their point of view on MON810. It will be examined how and to what extent MON810 was constructed as a risk.

4. Critical Discourse Analysis

As earlier parts of this paper have demonstrated, communication is of vital importance in the portrayal of risks. It can serve to construct a risk by attaching values to purely technical features. In order to understand how this is done by various actors, the following section sets forth to analyse the discourse of various actors involved in the German ban of MON810. We chose to follow the discourse-historical approach to critical discourse analysis (CDA) in order to uncover patterns visible in messages transmitted by Monsanto – the risk producer – criticizing the ban, German politicians justifying the ban, the media, who transmit information to the public and risk contesters active in Germany. It should be noted that the relationship between discourse and socio-political practice is a dialectical one, which means that what is said influences what is done and the other way around. When analyzing discursive activities, these should not be understood only as the product of individual deliberations but also informed by social values and meanings. Individual authoritative actors can, thus, to a certain extent, control the discourse, but should be conceived as subjects rather than masters of the discourse (Jäger, 2001, p. 37). SARF allows for an understanding of risk construction as a matter of discourse, where individual actors – sources, transmitters and recipients – produce a risk message which is simultaneously informed by social norms and values. Hence, it enables us to deconstruct the process in which a social definition of risk emerges which deviates strongly from scientific assessment. Risk construction should therefore not be understood as a process only driven by individual intentions, but is also informed by its wider social context.

The first step of our analysis is a 'first order critique' which wil help us to uncover textual story lines, inconsistencies and silences or non-expressions (Meyer 2001, p. 26; Jäger 2001, p. 34; Wodak 2001, p. 65). Secondly, we will subject the findings from the first section to a 'second order critique' in which we wil contextualize the discursive patterns in their wider socio- political context. This section will be rather interpretive and relate our findings to the conceptual and theoretical debate on uncertain risks.

The purpose of this analysis is to show how the actors' use of science influenced the social construction of risk. In order to account for the multi-actor situation, we will analyse

the influence of the most important communicators on risk construction surrounding MON810. Monsanto as the risk producer and GMO proponent will be taken into account. Since politicians have to justify their regulatory decisions, their discourse activities also need to be included in this analysis. It is mostly the media which take on the role of the transmitter between politicians/decision-makers and the public. Thus, scrutinizing the display of MON810 in a selection of online versions of mainstream newspapers adds this dimension to our case study. Lastly, risk protesters, such as environmental NGOs, play an important role in the dialogue on GMOs.

4.1 First-Order Critique

Within the discourse surrounding MON810, we can observe three closely connected logics which influenced the way in which the different actors approached science in the construction of their arguments. This process of argument construction is neither linear nor is there a necessary causal relationship between the observed patterns. The first logic is that actors expect 'plausibility proofs', meaning that they assume science to provide definite and conclusive answers to closed questions. An interlinked pattern is the representation of science as a superior authority. A third related pattern is that the actors remain silent on uncertainty. We regard these patterns as constitutive elements of the social process of risk construction.

a. Plausibility Proofs

In a press release, the Federal Minister of Consumer Protection emphasized that any policy approach must ensure that "any use of argrobiotechnology . . . is completely safe" (Aigner, 2009). Equally displaying the expectation that science can provide certainty, the Bavarian Minister President called on experts to clarify "all open questions" (Focus, 2009a).[17] Interestingly, this line of thought is present independently of party lines. The then Environmental Minister pertaining to a different party, for example, claimed that "first al doubts on the environmental effects of MON 810 should be erased"[18] before the commercial cultivation of MON 810 could be reconsidered (Focus, 2009a). The media exposed the same logic, for instance by posing simplistic and closed questions such as "how dangerous are such manipulations for the environment, humans and animals? Can these artificial interferences with genetic materials cause unimagined harm to humans or the environment?"[19] (Hamburger Abendblatt, 2009). Another example for this can be found in the newspaper *Frankfurter Allgemeine Zeitung* (FAZ) which asked "how threatened is the environment in reality?"[20] (2009). The omnipresent expectation of plausibility proofs indicates that science is seen to provide 'truth'. Thereby, it is arguably elevated above all

other sources of knowledge. The depiction of science as providing superior authority is another recurring discursive pattern.

b. Science as Providing Ultima te Authority

In order to discredit the German ban, Monsanto first highlighted the procedural requirement of the safeguard clause which states that a ban has to be motivated by new scientific evidence. According to the risk producer, the safety of its product is confirmed by "an overwhelming body of evidence" which has been "repeatedly confirmed" by "competent authorities" (Monsanto, 2009a, b). The authority of this argument is further reinstated by drawing a dividing line between Monsanto's science and the science used by the German authorities in order to justify the ban. Monsanto stated that this ban was not "supported by any *convincing* scientific evidence" (2009a). When talking about the court case, Monsanto hopes that "there is room for scientific argumentation within this framework",[21] and thus implies that this has not been possible in the debate before (Sueddeutsche Zeitung, 2009). Moreover, Monsanto's managing director for Northern Europe makes it clear that she regards the decision to ban MON810 in Germany as a politically motivated one, in sharp contrast to a scientifically justified one: "the political environment has radically changed . . . I think she [the Minister for Consumer protection] acted in the clear intention of [party comrades] . . . [and] the arbitrary ban is not substantiated through convincing scientific proofs" (Monsanto, 2009c).[22] Furthermore, Monsanto presents itself as a victim of a "breakout of true hostility towards technology in Germany" which prefers precaution over anything else (Sueddeutsche Zeitung, 2009).[23] It implies that Monsanto does not stand any chance - despite scientific evidence indicating the safety of its product- against the regulator. Thereby, the company presents itself as a rational actor confronting the value-driven and emotional sentiments transmitted by German politicians. Consequently, Monsanto depicts scientific arguments as the only valid ones.

The German risk manager exhibited a similar depiction of science. The Minister for Consumer Protection insisted that "contrary to other assertions, my decision is not political. It is a technical decision and is moreover required to be so for legal reasons" (Aigner, 2009). In this case the use of the word 'technical' implies superiority of scientific rationales over political ones. Moreover, it seems to be regarded as providing justification to a degree where no further elaboration on the nature of the respective scientific evidence is required: the Minister emphasized that there were "justifiable grounds" for the ban of MON810 without explaining the precise grounds (Aigner, 2009). Similarly, a party comrade called the ban "a very important, technically founded decision"[24] (Der Spiegel, 2009a) and emphasized that "we . . . do not want [MON 810] given the current *state of science*"

(Die Welt, 2009, emphasis added).[25] Taken together, all these statements exemplify that justifications are easily made with reference to science as the latter is seen as a superior source of authority.

The media also follows this logic of regarding science as providing ultimate authority. They depict science as factual and therefore superior to 'politics' or 'ideology'. Monsanto's studies were called into question by the German newspaper, *Hamburger Abendblatt*, which emphasized that "while the producers point at *their own* risk studies, the opponents collect evidence from the *most diverse* scientific institutions" (2009, emphasize added).[26] The company's assessment and monitoring were label ed as "questionable" and it is highlighted that a scientific institute made it explicit that Monsanto's data interpretation is flawed (Tagesspiegel, 2009).[27] The notion of the scientific invalidity of the ban is strengthened by label ing it a "purely political decision" (Taz, 2009)[28], which was taken due to "inner party pressure" (Tagesspiegel, 2009).[29] The scientific justification is seen as a superficial argument trying to conceal the underlying political pressure by party comrades and GMO-opponents (Die Zeit, 2009a,b; Focus, 2009a,b; Der Spiegel, 2009a).[30] Moreover, the position of the GMO opponents is contrasted to that of 'science' by label ing it a "quasi-religious movement" which plants "seeds of fear" about the "devil's maize [MON810]" (Die Zeit, 2009a,b).[31] The media argues that "politics surrendered to ideology" and "used populist sentiments of GMO-opponents" in order to justify their ban, despite scientific evidence pointing to the safety and usefulness of MON810 (Die Zeit, 2009a,b).[32] Here, the opposing view is presented as a value-driven, irrational one, denying the facts produced by scientists. By repeatedly drawing a value-fact distinction, the media presents science as a superior source of knowledge.

Another significant actor in the debate surrounding MON810 were non-governmental organizations. A Greenpeace spokeswoman underlines her support for the ban by claiming that "numerous scientific studies have shown that the genetically modified maize presents a danger for the environment".[33] Neither the content nor the source of the scientific studies in question are mentioned, instead 'scientific studies' are positioned as an unquestionable source of truth. Moreover, a big part of the conducted research is claimed to "be controlled by the companies through patents or the declaration of results as company secrets" (Greenpeace, 2009).[34]

In this debate in which science is regarded as providing 'truth', it was commonly utilized to legitimise points of view and discredit others. With reference to science, actors presented their arguments as factual and thereby rhetorically elevated them above other claims. The acknowledgment of uncertainty is incompatible with these claims as it would exhibit the limits of science in providing 'truth'. Another pattern we could observe

accordingly was that the different actors avoided or crowded out uncertainty in their speech acts.

c. Uncertainty as a Non-Expression

In line with the authority claims and plausibility proofs, uncertainty, whether in explicit or implicit terms, is avoided by the risk producer in its communications about MON810. The term uncertainty itself cannot be found in any of the press releases or statements made by Monsanto and neither does the company refer to it implicitly. Hence, science is presented as a uniform block that can only express one, 'true,' solution which, in the case of MON810, is that the maize form is safe. Nowhere in its press releases or statements does Monsanto acknowledge the possibility of value-judgements being inherent to science or the possibility that science may not always be able to produce conclusive evidence. Quite to the contrary, the terms 'safety' and 'safe' are omnipresent and suggest that they can indeed be provided by the 'superior authority' of science.

As the risk manager emphasised, the decision to ban MON810 was a "technical one" and had to be so "for legal reasons" (Aigner, 2009). For the German decision-makers it was thus of similar importance to uphold the image of science as a provider of truths and facts and therefore avoid uncertainty in the discourse. There are no statements which admit, neither implicitly nor explicitly, that scientific uncertainty about risks posed by MON810 remain, although the risk managers were surely aware of the scientific pluralism.[35]

The risk protesters also remain silent on uncertainty by presenting MON810 as "entailing too high risks for the environment" (BUND, 2009).[36] Greenpeace stresses the danger of the GMO without indicating attached uncertainties: "MON810 inherits dangers for the environment, because it produces a toxic, which is not just deadly to the vermin European corn borer" (Greenpeace, n.d, p.1).[37]

We have repeatedly identified an equation of uncertainty with risk - an observation in line with findings by i.a. van Asselt and Vos (2008). Through this equation, the nature of *uncertain* risks is ignored since possibility is confused with certainty. Risk managers, the media and risk protesters expose this pattern. The Minister for Consumer Protection justifies her ban on the basis of "new evidence [that MON810] endangers the environment" (Der Spiegel, 2009b).[38] On the part of the media, the *Hamburger Abendblatt*, for instance, states that "the risk for the butterflies cannot be assessed conclusively . . . is a reason why the maize . . . may no longer be cultivated in Germany (2009).[39] In similar vein, a Greenpeace and Friend of the Earth Report concluded that uncertainty necessitates a recommendation for non-cultivation (2009, p.3).

4.2 Second-Order Critique

The preceding section has analysed the construction of risk associated with the GM maize MON810 in Germany. More specifically, by focusing on the use of language, it has shown how an uncertain risk, as technically defined, has been socially constructed as a known risk. We have identified that the risk producer and certain media representations regard the product as safe while the risk managers and protesters view it as a danger. In spite of their diverging definitions, the different actors exposed common patterns of risk construction. First, by demanding plausibility proofs, all actors approached science as if it was able to provide certainty. If science is seen as providing truth, it follows that it is superior to all other sources of knowledge. The representation of science as the ultimate benchmark of political decisions therefore constituted a second omnipresent pattern. As the former two findings suggest, there could be no recognition of uncertainty in the discourse surrounding MON810. A third dominant pattern therefore consisted in the crowding out of uncertainty. These patterns exhibit the uncertainty paradox as defined by van Asselt and Vos (2006, 2008). In the following we will contextualize these patterns in the light of current practical and normative debates on EU risk governance.

The first two patterns – plausibility proofs and science as a superior authority – can be understood as boundary work. According to Gieryn (1983, 1999), the notion of boundary work relates to the drawing of distinctions between different realms, such as science versus non-science or versus politics or ideology. Through this contrast, self-evident justifications are created and maintained and, at the same time, help to construct superiority of claims. We argue that this can be done explicitly as well as implicitly. In the case of MON810, the expectations of plausibility proofs established science as a source capable of providing 'truth' which implies that science is *above* all other sources of knowledge. This constitutes an implicit boundary between sources of evidence and establishes a hierarchy between them. Accordingly, science, as a producer of 'truth' is the self-evident choice for actors demanding answers and warranting claims. Our first-order critique revealed that regulators turned to science to clarify "al open questions" (Focus, 2009a). This stands in stark contrast to the rationale of the new participatory model and PNS which contend that science is an insufficient base for decision-making and should be supplemented by non-scientific considerations. Interrelated, explicit boundary work is manifest in statements suggesting that science can provide superior authority to their claims. The actors involved in the discourse surrounding MON810, articulated boundaries between science and politics and between science and ideology. This tendency is exemplified by media reports that depicted GM opponents as a "quasi-religious movement"[40] (Die Zeit, 2009a,b) as opposed to 'sober' science. In contrasting these realms, they constructed a superiority of rational scientific facts over political or ideological considerations.

The third pattern – avoidance or crowding out of uncertainty- can be understood as an expression of uncertainty intolerance on the part of the different actors. This relates to situations in which scientific uncertainty is "not acknowledged deemed irrelevant or . . . simply evaded" (van Asselt and Vos, 2008). The logic that uncertainty equals risk and the presentation of uncertainty as a monolithic block manifest this intolerance (cf. Van Asselt and Vos, 2008). Uncertainty intolerant speech acts crowd out uncertainty from the discourse and thereby help to construct a risk that is perceived to be certain or known by the wider society.

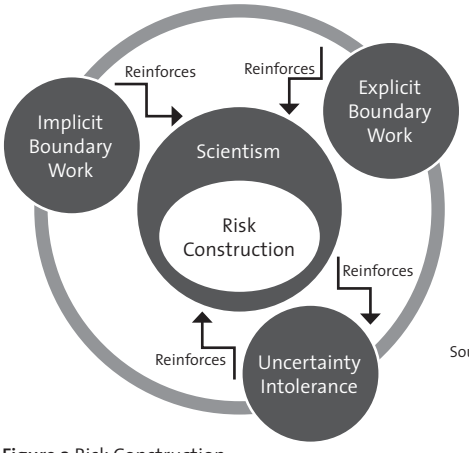
We thus observe a strong discursive tendency to prioritise scientific findings over all other statements. This notion that "facts and values are distinct entities and that facts, unlike values, are beyond dispute" has been termed 'scientism' (Kleinman and Kinchy, 2003, p. 585). Scientism includes three main assumptions: the superiority of facts over values, the neutrality of science and the idea that science is the best basis for decision-making. Within this scientism discourse, actors were able to instrumentalise science for the justification of political arguments. The central example for this is the official statement of the German authority that the decision to ban MON810 was a "purely technical decision" (Aigner, 2009). As our first-order critique has shown, the other actors similarly used science to give their arguments a factual disguise.

The discursive tendencies which we have identified arguably reflect and reinforce some of the most pressing problems of the new participatory model of EU risk governance. The institutional separation of risk assessment and risk management and the opening up of both processes to public deliberation entailed that now a myriad of scientific and social perspectives have to be accounted for in decision making. As our case study has exemplified, social actors now can access relevant information at an early stage and mobilise their 'own' science in order to construct versions of risk which justify their political arguments. This arguably engenders a pluralism of science in which it is difficult for lay people to differentiate between scientific sources according to quality (De Marchi and Ravetz, 1999; Löfstedt et al., 2011). In turn, regulators are able to pick and choose the scientific claims which best fit their arguments. This may lead to suboptimal policy outcomes because neither scientific nor social rationales are adequately incorporated into decision-making (Renn, 2001; Löfstedt, 2005). At the same time a discourse like the one on MON810 in Germany in which every actor presents his science as the only true one in spite of uncertainty, the confusion and uncertainty resulting from this pluralism is arguably amplified. This undermines the rationale of the new participatory model which had been designed to promote transparency and trust. By allowing for the instrumentalisation of science and the exclusion of uncertainty in communication, the model rather gave

way to the erosion of transparency and a polarisation of the debate. Hence, in line with Renn (2001), we argue that, given the current conditions, it is increasingly difficult to find consensual risk choices that are acceptable for society at large. We would like to term such a situation in which pluralism without a hierarchy and the consequent possibility that science is instrumentalised in combination with an erosion of transparency one of *uncertainty amplification*. In this context we understand uncertainty in its rather plain word meaning of denoting confusion and a lack of clarity.

Furthermore, it can be argued that the erosion of transparency, fuelled by a scientism discourse, is problematic from the angle of normative democracy. This is because it helps to avoid accountability of decision-makers. By enabling regulators to 'arbitrarily' draw on scientific sources to justify their claims, it shields the underlying political rationale from public scrutiny. In summary, the quality of the decision may be compromised as neither social nor scientific standards are sufficiently accounted for. This is in line with Renn's contention that the quality of political solutions can only be ensured if the "best expert knowledge about potential consequences of each decision option" as wel as a "reflection and processing of all relevant opinions and evaluations put forward by stakeholders and affected citizens" are included (2001, p. 429).

We argue that the process of risk construction has been strongly influenced by a scientism discourse. Scientism has been reinforced by implicit as well as explicit boundary work. In addition, there is a mutually reinforcing relationship between uncertainty intolerance and scientism. While the conventional conception of science fuels uncertainty intolerance and allows for authority claims, the crowding out of uncertainty reinforces the image of authoritative science.



Source: Authors

Figure 2 Risk Construction

This, in turn, highlights several chal enges. First of al , 'supermarket thinking' (Renn, 2001) reflects the tendency of different actors to 'pick and choose' scientific evidence in order to buttress their political intentions. In similar vein, a value-inclusive debate was avoided. Both mechanisms potentially lead to suboptimal policy outcomes. Moreover, there is a general confusion about whose science is to be trusted and can be relied upon as, for example, an integrating rationale for science is missing (Renn, 2001). At the same time, decision-makers may be able to avoid accountability. Arguably, we are thus presented with practical and normative deficits. By introducing scientific pluralism, the new participatory model therefore presents us with these deficits as long as uncertainty is not incorporated within public and political discourses.

In our view, the problems caused by a scientism discourse can only be adequately dealt with if there is a wider acknowledgment of scientific pluralism and uncertainty which characterize the era of post-normal science. It is clear that uncertainty *tolerance* is conditioned by an acknowledgment of uncertainty. Moreover, regulators will only be held accountable for their scientific rationales, if the wider public is aware of scientific pluralism, i.e. of the presence of alternative scientific arguments. This requires a changed understanding and representation of science which enables the accommodation of uncertainty in the discourse. In the next section, we would like to point at some potential trajectories to include uncertainty into risk governance identified by several scholars in order to balance scientific and social dimensions.

5. Recommendations

As risks are the "bel wethers" of decision-making (Kasperson et al., 1988), their construction is crucial to policy outcomes. It has been demonstrated that uncertainty intolerance and scientism have helped to construct an uncertain risk as a known risk and an inherently political decision could therefore be presented as a self-evident technicality. It is, however, desirable that decisions are value informed. Risk communication should therefore be uncertainty *tolerant*. If uncertainty is acknowledged by a wider array of social actors, it is more likely that value considerations will supplement scientific rationality. Our main trajectory is consequently to improve communication throughout the whole process of risk governance in order to sensitize all actors with respect to the limits of science. This would comply with the underlying rationale of the separation of risk assessment from risk management. Following the institutional separation, science no longer carries direct implications for decision making and thereby, at least in theory, creates room for non-scientific considerations.

Our recommendations hint at possible ways in which communication between risk assessors, managers and the wider public takes could be improved at different intersections. It should be noted, however, that risk governance is not a linear three-stage process, but that dynamic interactions between realms of assessment, management and communication are needed (van Asselt and Renn, 2011). Due to the potentially infinite number of intersections, our recommendations cannot be exhaustive, but nevertheless might provide further input for the development of guidelines.

In general, it has been widely acknowledged that traditional top-down risk communication aimed at bringing public perceptions in line with expert opinion is no longer viable (Renn, 2006; Löfstedt, 2005). Rather, effective risk communication should be based on a two-way exchange of views and mutual learning. This means that a professional community should take into account alternative positions and risk management practices as well as existing public perceptions. In doing so, problems with processing scientific information should be identified and accounted for in conveying risk information. Moreover, attached social values and interests should be identified prior to assessment and management so that expert opinion and policies actually address the concerns of society. In this way, tailor-made risk communication strategies can be developed that effectuate a profound understanding of the uncertainties involved. In order to realize this, interaction between risk assessors and the public at an early stage is of vital importance (Renn, 2006, p.54; Renn and Walker, 2008, p.xxv; Johnson 2008). The ultimate goal of risk communication should thus not be to educate citizens, but to assist them "in understanding the rationale of risk assessment results and risk management decisions, and to help them arrive at a balanced judgement that reflects the factual evidence . . . in relation to their own interests and values" (Renn, 2006, p.54-55). Based on the awareness of uncertainty, both, those who are central to the risk management process and society at large should thus make their value- informed judgements which are then to feed back on decision making.

More specifically, we suggest two means which conform to the underlying rationale of risk communication as outlined above. In our view, the establishment of an overall framework for risk communication could be enhanced by the introduction of a uniform language 'code'. This could be modelled on the Intergovernmental Panel on Climate Change (IPCC) reports which provides for a format according to which likelihood and confidences are to be expressed. The general idea was to develop a scheme on which uncertainty information could be expressed in uniform terms (Risbey & Kandlikar, 2007, pp.19-21). As a result, the uncertainty information could be transmitted in a clearer and more understandable way which could counteract the erosion of transparency and

improve the overall process of risk communication. Confusions between uncertainty and risk could be avoided.

With the help of a uniform language surrounding scientific uncertainty, actors involved in risk governance could, from 'framing' onwards, define the problem surrounding the uncertain risk in unambiguous terms. According to Dreyer and Renn (2009, 2010) so-called interface stages could provide further assistance in this process. The stage of framing is very important as it could tackle the problems associated with uncertainty intolerance and scientism by the roots through expressly taking societal values into account. It should therefore involve society and scientists in order to ensure that science answers the 'right' questions, i.e. those society deems the most pressing. A second stage proposed by the two authors consists of an evaluation after risk assessment. At this stage, both, scientific and societal arguments should be taken into account when judging the acceptability of the risk. In this way an open dialogue involving science and society is created without falling back into the old technocratic model (2010, pp. 19-20).

Moreover, we would like to argue in line with Löfstedt et al's (2011) account of improved official risk communication. Official risk assessment bodies like EFSA should improve their public profile and engage in more proactive and audible risk communication. This is necessary, since official bodies like EFSA increasingly lose their influence on public risk definition vis-à-vis other stakeholders due to their inferior communication skills (Löfstedt et al, 2011). Against this background, the authors propose a number of strategies to improve official risk communication. Firstly, they argue that regulators are often too slow to communicate in comparison to other actors. The reason for this lies in the vast bureaucratic machineries that make up most government departments. It would therefore be useful to reduce the bureaucratic barriers to efficient communication. Moreover, they suggest that officials should be "encouraged to attend risk communication courses" in order to improve their capabilities (p. 421). Secondly, official bodies like EFSA should promote an understanding of their high scientific standards, since in media discourses scientists are often pitted against each other, regardless of their scientific credentials (p. 422). Thirdly, in order to ensure that the risk assessment of official assessors is of the highest quality - and is therefore less likely to be undermined by stakeholders and special interest groups - it would be advisable to subject all scientific results relevant to decision making to strict scientific peer review (p. 423).

In our view the underlying problem is how science is understood and used by the different actors involved in risk governance. The preceding proposals could arguably help to sensitise the institutional process as well as the public discourse for uncertainty. In combination, these might help to foster a broader acknowledgement of the limits

of science and the related importance of social rationales to decision-making. Taken together, we envisage a discourse that helps to forge consensual decisions and thereby to prevent societal ruptures. In line with Renn (2001), such a discourse should aim to create common knowledge informing common reflections. These reflections should, in turn, clarify relevant preferences and values and ultimately generate consensual regulatory solutions. Given such a discourse pressure on regulators would arguably rise to disclose the political motivations of their decisions and prohibit them to (mis-)use science as a universal and self-evident justification.

6. Concluding Remarks

Uncertain risks increasingly confront decision makers with the task of forging adequate regulations on new technologies, products or developments. Since under conditions of uncertainty, science is unable to yield conclusive evidence, the academic debate has increasingly acknowledged that in the era of pots-normal science regulations on uncertain risks must be informed by social, economic and cultural values and interests. The risks which are to form the basis of decision making thus need to be defined in terms of scientific *and* social considerations. The new participatory model of risk governance as applied in the area of EU food safety incorporates this insight by building on an institutional separation of risk assessment and risk management. In this way, the technical dimensions of probability and magnitude are to be supplemented by societal choices on acceptability. By drawing on SARF we have developed an understanding of risk construction as a discursive process in which technical and social views interact to produce definitions of risk.

Our study examined the process of risk construction in the case of the German ban on MON810. It was highlighted that an originally uncertain risks has been constructed as a know risk. We have argued that the process of risk construction has been strongly influenced by a scientism discourse and the mutually reinforcing relationship between uncertainty intolerance and scientism. While the conventional conception of science fuelled uncertainty intolerance and allows for authority claims, the crowding out of uncertainty reinforced the image of authoritative science. In this way, reference to science was used to display a political decision as a technical one. Our modified understanding of SARF enabled us to discern this instrumentalisation of science and uncertainty, a process usually overlooked in the traditional understanding of SARF. This instrumentalisation may, in fact, inhibit a fuller determination of risk as it discursively delimits the factors taken into account. The

supplementation of technical properties of a risk with social dimensions which is envisaged as a positive trait of social risk construction by SARF, may thus be hampered.

We think that uncertainty intolerance and the present displays of science are due to an 'outdated' conceptualisation of science which neglects the possibility of value-judgments within science and the fact that uncertain risks have to be regulated according to their *social* acceptability. Before uncertainty *tolerance* can exist and be communicated effectively, these qualities of uncertain risks have to be incorporated within the regulatory framework. Post-normal science as a sensitizing concept might prove to be helpful in this respect.

Overal , the case of Germany's ban on MON810 revealed that the current risk governance process is still not fit to adequately deal with the challenges posed by uncertain risks. We emphasized several challenges which resulted from the way in which MON810 has been constructed as a known risk. 'Supermarket thinking' and the exclusions of values from the debate potentially lead to suboptimal policy outcomes and decision-makers may, at the same time, be able to avoid accountability. In addition, the lack of an integrating rationale for science may lead to situations of uncertainty amplification, polarise debates and even lead to ruptures in society. In order to counteract these practical as well as normative deficits, we suggested general and specific trajectories aimed at improving communication on and understanding of uncertain risks. Ultimately, we envisage that the institutional process and the public discourse are sensitised for uncertainty in order to improve decision-making and accountability. This is to provide for risk choices which represent the interests and values of the largest possible number, thus avoiding societal ruptures and ensuring the democratic quality of EU risk governance.

Endnotes

1. Please see Section 2 for more details on the authorization process.
2. E.g. Austria banned MON810 as early as 1999 (European Commission, n.d.).
3. Germany invoked the safeguard clause provided by Article 23 of Directive 2001/18 and Article 34 of Regulation 1829/2003 in order to enact the ban.
4. An overview of the different variants, a map of where they are cultivated or released and information for previous years can be found via the BVL website (BVL, 2011).
5. See Recitals (1) and (2) of the GFL.
6. The separation is contained in Art. 6, the definitions of what the EU understands as 'risk analysis', 'assessment' and 'management' in Art. 3 (10), (11) and (12) of the GFL.
7. See Recital (19), Art. 3(12), Art. 6(3), Art. 7 of the GFL.

8. It is supplemented by Regulation 1830/2003 which stipulates rules for the traceability and labeling of GM products placed on the market.
9. In addition, in the case of GMO authorization for cultivation, Member States are responsible for the initial environmental risk assessment.
10. Art. 23 of Directive 2001/18, which requires new scientific evidence indicating that a GMO constitutes a risk to human health or the environment, and Article 34 of Regulation 1829/2003, which presupposes that a GM product constitutes a serious risk to human or animal health or the environment.
11. Moreover, products originating or containing MON810 (i.e. MON810 in the form of derivatives for human consumption) are authorized pursuant to Regulation 258/97. The use of food additives made fr om MON810 is allowed under Directive 89/107. Since the German ban concerns cultivation only, the other areas will not be explored further in this paper.
12. Authorized under Directive 90/220 or Regulation 258/97 respectively.
13. Austria, Hungary, Luxembourg, France, Greece and Germany (European Commission, n.d.).
14. The Commission tried several times to repeal the national safeguard measures, but the Council upheld them by QMV (European Commission, n.d.,a).
15. This is in accordance with §14 Abs 5 Gentechnikgesetz which provides that GMO authorizations granted by competent EU Member State authorities have the same effect in Germany as authorizations granted by the competent German authority. "Der Genehmigung des Inverkehrbringens durch die zuständige Bundesoberbehörde stehen Genehmigungen gleich, die von Behörden anderer Mitgliedstaaten der Europäischen Union oder anderer Vertragsstaaten des Abkommens über den Europäischen Wirtschaftsraum nach deren Vorschriften zur Umsetzung der Richtlinie 2001/18/EG erteilt worden sind."
16. Art. 23 of Directive 2001/18 and Art. 34 of Directive 1829/2003.
17. "Bayerns Ministerpräsident Horst Seehofer (CSU) sagte: Neue Studien zwingen uns dazu, die offenen Fragen erst einmal zu klären" (FOCUS, 2009a).
18. "Bundesumweltminister Sigmar Gabriel (SPD) sagte, zunächst sollten alle Zweifel über die Umweltverträglichkeit von MON 810 ausgeräumt werden . . ." (FOCUS, 2009a).
19. "Doch wie gefährlich sind solche Manipulationen für Umwelt, Menschen und Tiere? Können die künstlichen Eingriffe ins Erbgut . . . ungeahnte Schäden an Menschen oder an der Umwelt anrichten?" (Hamburger Abendblatt, 2009).
20. "Doch wie gefährdet ist die Umwelt wirklich?" (FAZ 2009).
21. "Wir hoffen, dass in dessen Rahmen auch wissenschaftlich argumentiert werden kann" Ursula Lüttmer - Ouzane in an interview with the Süddeutsche Zeitung. (Sueddeutsche Zeitung, 2009).
22. "Das politische Umfeld hat sich in den vergangenen Jahren radikal geändert. Noch vor kurzem erlebten wir eine CSU, die stark hinter der grünen Gentechnik stand. Aber das hat sich zuletzt leider komplett gedreht. Man sieht doch, wie ein Herr Seehofer gestrickt ist. Er schaut auf die Stimmung im Volk. So kam es, dass Partner, die uns früher unterstützt haben, jetzt eine absolute Kehrtwende gemacht haben. Ich denke, sie [the Minister for Consumerprotection] hat in der klaren Intention der Herren Söder und Seehofer

gehandelt." Ibid; "Das willkürliche Verbot von MON 810 durch Bundeslandwirtschaftsministerin Ilse Aigner ist nicht durch überzeugende wissenschaftliche Beweise untermauert, die eine solche Maßnahme rechtfertigen würden." Monsanto Press Release from 5 may 2009. (Monsato, 2009c).

23. "In Deutschland ist in der letzten Zeit vielmehr eine wahre Technologiefeindlichkeit ausgebrochen. Immer heißt es: Lieber tun wir etwas nicht, bevor wir nicht wissen, was es in letzter Instanz bedeutet." (Sueddeutsche Zeitung, 2009).
24. "… eine ganz wichtige, fachlich begründete Leitentscheidung" (Der Spiegel, 2009a)
25. "Wir in Bayern wollen das bei dem derzeitigen Forschungsstand nicht", sagte Seehofer (Die Welt, 2009b).
26. "Während die Hersteller auf eigene Risikostudien verweisen, sammeln die Gegner Indizien aus verschiedensten Forschungsinstitutionen" (Hamburger Abendblatt, 2009).
27. "Fragwürdig is aber auch, wie Monsanto den … Monitoring Bericht … zusammengetragen hat … Das Hemholtz-Zentrum for Umweltforschung, das gemeinsam mit der Gesellschaft für Schmetterlingssc hutz und der Internetplattform Science 4 you die jährliche Falterzählung betreut, weist jedoch ausdrücklich darauf hin, dass eine solche Interpretation aus den Daten … nicht abzuleiten sei" (Tagesspiegel, 2009).
28. "Das war eine rein politische Entscheidung" (Taz, 2009).
29. "Entsprechend wird Aigner aus ihrer Partei unter Druck gesetzt, den Anbau zu verbieten" (Tagesspiegel, 2009).
30. "Hintergründig wird Ilse Aigner [the Minister for Consumer Protection] nämlich von der heimischen CSU in München unter Druck gesetzt" (Die Zeit, 2009a). "Und die deutsche Politik tut heute ihr Bestes, um es den Gentechnik-Kritikern so weit wie möglich recht zu machen" (Die Zeit, 2009b). "Der Druck aus der CSU, den Genmais zu verbieten, war in den vergangenen Wochen größer geworden" (Focus, 2009a). "Als treue Vollstreckerin ihres übermächtigen Parteichefs Horst Seehofers … legte die junge Bundesministerin [Aigner] die Argumentation dar… Die Mimik zeigte: Der Druck muss enorm gewesen sein" (Focus, 2009b). "Eigene [Aigners] Überzeugung sieht wohl anders aus" (Der Spiegel, 2009a).
31. "Teufelsmais" (Heading, Die Zeit, 2009a)." "Einiges spricht dafür, dass es sich bei der Anti-Gentechnik-Lobby um eine quasireligiöse Bewegung handelt." "Die Saat der Angst ging auf" (Die Zeit, 2009b).
32. "Mit dem Anbauverbot für MON810 erliegt die Politik der Ideologie." "Die Politik macht sich hier in populistischer Absich die Stimmungsmache der Gentechnikgegner zunutze" (Die Zeit, 2009a).
33. "Zahlreiche wissenschaftliche Studien belegen, dass der Genmais eine Gefahr für die Umwelt darstelle" (Der Spiegel, 2009b).
34. "Letztlich kontrollieren die Konzerne große Teile der Forschung über Patente oder darüber, dass sie Forschungsergebnisse für Betriebsgeheimnisse erklären." (Greenpeace, 2009)
35. While the German authorities justified the ban on the basis of two studies, EFSA came to the conclusion that MON810 was as safe as conventional maize (EFSA, 2009). Several other studies, for example Ricroch 2009 and an opinion provided by the German agency for biological safety (ZKBS 2009), came to the conclusion that a ban could not be justified on the basis of current scientific findings.
36. "In Deutschland wurde der Anbau im April 2009 verboten – wegen zu großer Risiken für die Umwelt." (BUND, 2009).

37. "MON810 birgt Gefahren für die Umwelt, da er ein Gift produziert, das nicht nur tödlich auf den Schädling Maiszünsler wirkt." (Greenpeace, n.d., p.1).
38. "Sie [Aigner] habe berechtigten Grund zu der Annahme, dass . . . MON810,eine Gefahr für die Umwelt darstellt"(Der Spiegel, 2009b).
39. "Das Risiko für die Schmetterlinge lässt sich also nicht abschließend beurteilen; dies ist einer der Gründe, dass der Mais . . . nicht mehr wachsen darf" (Hamburger Abendblatt, 2009).
40. "Teufelsmais" (Heading, Die Zeit, 2009a). "Einiges spricht dafür, dass es sich bei der Anti-Gentechnik-Lobby um eine quasireligiöse Bewegung handelt." "Die Saat der Angst ging auf" (Die Zeit, 2009b).

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Academic Year 2011–2012

Trust-Building Risk Communication in the Post-Trust Era

On the Importance of Accountable Risk Communication for the GM Food Producing Industry

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1. Introduction

In the 1990s, several food safety scares in many Western countries caused the public to lose confidence in the ability of governmental food safety regulators to effectively prevent similar events from occurring in the future (Eldridge et al., 1998; Gaskell & Bauer, 2001; Poortinga & Pidgeon, 2005; Gaskell et al., 2003). This profound loss of confidence in public food safety regulators signalled a change in the European societal climate away from the trust-era toward the post-trust era[1] (cf. Frewer et al., 1996; Peters et al., 1997; Frewer et al., 1998; Hunt & Frewer, 2001; Gaskell et al., 2003; Löfstedt, 2004; Rosati & Saba, 2004; Löfstedt, 2005). Within this new societal climate stakeholders[2] no longer blindly rely on regulators but instead themselves demand insights into the regulatory process to see that they are not being exposed to any unacceptable risks. To better accommodate this wish, a new regulatory model[2] has emerged, which is characterised by horizontal relationships among the various stakeholders and a dispersion of responsibilities (Majone & Everson, 2001; Löfstedt, 2004; van Asselt & Vos, 2008; Dutch Scientific Council for Government Policy, 2009; Löfstedt et al., 2011; Renn et al., 2011; Drott et al., 2012). Drott et al. (2012), however, argue that this new and complex institutional arrangement is merely able to guarantee piecemeal accountability of the regulatory processes. For the novel food producing industry, this, coupled with the perceived inability of governments to effectively regulate risks, has the effect that it can no longer derive its trust indirectly from the trust in government agencies or the overall institutional arrangements.

This situation is all the more important in the GM food[3] sector, which particularly in Europe suffers from substantial trust problems (Gaskell & Bauer, 2001; Poortinga

1 While in today's post-trust era, most regulators as well as the entire regulatory system have lost the trust of the public in many European countries, there continue to be some exceptions. For instance, government regulators and 2 Stakeholders here are defined as "[persons] with an interest or concern in something" (Oxford Dictionary, 2012a). In the post-trust society, this group primarily consists of the government, related businesses, non-governmental organisations (NGOs), the media and the general public, more specifically of consumers and clients. See also Regester and Larkin (2005, Figure 2.1.) for an illustrative overview over relevant stakeholders.

2 It is debatable if this can be referred to as a model in the strict sense of the concept. In this context, a model is "a simplified description ... of a system to assist ... predictions" (Oxford Dictionary, 2012b). Renn et. al (2011) refer to it as the 'risk governance framework', thus avoiding the term model. 'Framework' is defined as the basic structure of a system (Oxford Dictionary, 2012c). However, the degree of concretisation or simplification is a question of margin. For our purposes, for the ease of our argumentation, we ignore this question henceforth and stick to the term 'model'.

3 'Genetically modified food' means food containing, consisting of or produced from GMOs"; 'genetically modified organism' or 'GMO' means a genetically modified organism as defined in Article 2(2) of Directive 2001/18/EC, excluding organisms obtained through the techniques of genetic modification listed in Annex I B to Directive 2001/18/EC (Art. 2(6) & Art. 2(5) of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed).

& Pidgeon, 2005; Gaskell, 2007,). More specifically, the GM food sector has recently been described as the "[a]chil es' heel of biotechnology"[4] (Gaskell et al., 2010, p. 7) and correspondingly is still targeted by large anti-GM food demonstrations. These protests, furthermore, receive relatively strong media coverage, which in turn further amplifies the critical perception of the public, which at best feels "uneasy" about GM food (ibid.). This stance also has substantial implications for the GM food producing industry, as, for instance, BASF - one of two firms that possess GM crops authorised for cultivation in the European Union - recently declared its withdrawal from the European market due to a persistent "lack of acceptance for this technology in many parts of Europe" (Keating, 2012). BASF's withdrawal from the European market once more illustrates that European consumers seem to distrust the GMO producers as wel as the institutional arrangements, which are in place to assure them of the products' safety.

In light of this, we argue that GM food producers, whose business relies heavily on the trust of their stakeholders,[5] have to take on a more proactive role to regain the lost trust. It is within this context that we seek to investigate how this very task may be accomplished. In more detail, we attempt to determine *how GMO producers can communicate their products risks so as to re-gain the trust of the public in today's post-trust era*. In this context, we hypothesise that *accountable risk communication can potentially help GMO producers in building a trust relationship with the public*. We framed the term *accountable risk communication* to allude to the fact that GMO producers should communicate the risks of their products to the public in a *transparent, inclusive* as well as *responsive* manner.

Given this focus, the paper is centred on the topic of trust in risk communication. In the first section of this paper, we provide a theoretical framework focused on three parts. We commence by firstly conceptualising trust in the context of risk communication. In so doing, we provide a working definition of trust and investigate the determinants of trust, in particular in the case when business has the role of a risk communicator.[6] Secondly, we conceptualise accountability and introduce the concept of '*accountable risk communication*'. Thirdly, we il ustrate a link between '*accountable risk communication*' and trust in the communicator. It is from this theoretical discussion that we derive our central

4 Whereas fifty-three percent of Europeans thought that biotechnology and genetic engineering have a positive effect, only twenty-three percent thought the same of GM food products (Gaskell et al., 2010, p. 16 & p. 37).

5 Otherwise a lack of trust can result in increased inspections by risk assessment agencies, risk amplification by the media, and fewer purchases by consumers and customers.

6 Throughout the paper, we will assume the perspective of business (i.e. the GMO producer or risk producer) as risk communicator. Hence, determinants of trust will be attuned to the specific case of business.

hypothesis outlined above. In addition, we conceive of an evaluation tool that can be used to assess the accountability of GMO producers' risk communication. In the second section of this paper, we present an empirical case study that adopts this theoretical framework to assess in how far the GM food producer Monsanto Company communicates risks of its GM food products in an accountable manner. These cases allow us to see whether our model can be applied to real-life examples of risk communication and to see whether there is a correlation with trust. Using the case study we, moreover, intend to illustrate the relevance of *accountable risk communication* for the GM food producing industry.

2. Towards a Trust-Building Risk Communication: A Framework for Business

We depart from the assumption that business' main interest is to make profits. In order to attain this goal, business needs to sell their products. In the field of GM food products, consumers have to be assured that they are not exposed to unacceptable levels of risk. Therefore, risk communication is crucial for the GM food producing industry, as it impacts on consumers' decisions on whether to accept or reject genetically modified food products. However, it is a consistent finding that risk communication will not be effective if the communication source is not trusted by the receiver (Slovic, 1993; Frewer et al., 1996; Löftstedt, 2006). Hence, trust is indispensable for business if it effectively wants to communicate that their GM products only feature acceptable levels of risks. A significant amount of research has already been conducted to illustrate the significant and positive correlation of trust in institutions responsible for managing risks (not only related to GM food) and the acceptability of risks on part of the wider public (Pijawka & Mushkatel, 1992; Bord & O'Connor, 1992; Flynn et al., 1992; Freudenburg, 1993; Jungermann et al., 1996; Siegrist, 1999; Siegrist et al., 2000; Poortinga & Pidgeon, 2005). The general consensus is that the causal relationship runs from trust to acceptability of risks.[7] As already outlined in the introduction, business is faced with the problem that in wide parts of the Western

7 However, this consensus has been challenged by Eiser et al. (2002) who found empirical evidence that acceptability of risk can also be the determinant of trust, not the result of trust. This reversed causality is referred to as "associationist view of trust" (Eiser, 1994 quoted in Poortinga & Pidgeon, 2005). The evidence is, however, mixed; some cases affirm the associationist view while others confirm the old consensus (cf. Eiser et al., 2002). Poortinga and Pidgeon (2005) provide additional evidence for Eiser's associationist view. However, they also cannot falsify the consensus view that trust causes acceptability of risks.

world, public trust in industry has declined (Frewer et al., 1996; Peters et al., 1996; Hunt & Frewer, 2001; Gaskell et al., 2003; Kjaernes, 2004; Rosati & Saba, 2004).

Consequently, faced with a general climate of distrust, producers of GM food products have to rebuild trust themselves. With this goal in mind, we firstly, however, require a thorough understanding of trust and its determinants. To this end, the first part of this section provides a conceptualisation of trust. This includes a distinction between different dimensions of trust and a composition of the most relevant determinants of trust.

Conceptualising Trust for Business

Renn and Levine (1991) suggest a particularly useful definition of trust in the realm of risk communication:

> *"Trust in communication refers to the generalized expectancy that a message received is true and reliable and that the communicator demonstrates competence and honesty by conveying accurate, objective, and complete information."*

(Renn & Levine, 1991, p. 179, in italics in the original)

This definition provides insights into the required qualities a communicator should possess – competence and honesty – as well as into the character of the communicated information itself – accuracy, objectivity and completeness. Further, Renn and Levine distinguish trust from the concepts of confidence and credibility, which are oftentimes used interchangeably. Confidence, however, is different in that it is defined as a "more enduring experience of trustworthiness over time" on a subjective or personal level. In other words, trust refers to the perceived truthfulness and reliability of a particular message from a risk communicator whereas confidence refers to the perceived truthfulness and reliability of all safety information coming from that same source. Lastly, credibility is defined as the "degree of shared and generalized confidence" in a communication source. Thus, a communication source gains credibility if many persons share confidence in it. Thus it is no longer a personal judgment anymore, but a collective perception.[8] Figure 1 shows the different dimensions of trust in form of an inverted pyramid:

8 A critical question in this regard is how many persons have to share a perception of confidence in a communication source for credibility to be assigned to that source. As there are always some sceptics, we would hold a safe majority to be a critical mass.

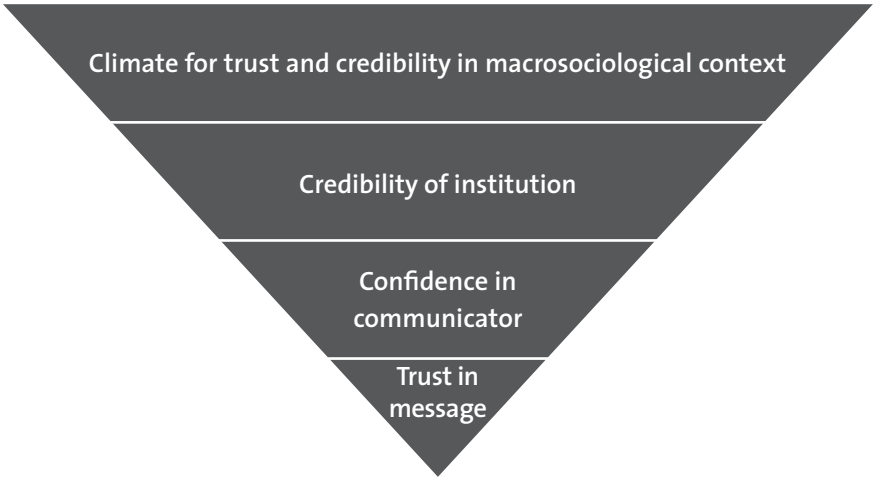

Figure 1 Inverted Pyramid of Trust. (Adapted from Renn & Levine, 1991, p. 181)

Looking from top to bottom of the inverted pyramid, the dimensions of trust are reduced in complexity and abstraction. Given this situation, it is comparatively easy to influence lower dimensions of trust through effective risk communication efforts, as those dimensions are more graspable. If the risk communicator succeeds in continuously communicating risks effectively, he can also attain confidence and eventually also credibility. While affecting these higher dimensions is a more intricate task, it is nevertheless one worth pursuing, as the higher the dimension of confidence and credibility, the higher will also be the initial trust in a message to start with. This is to say that the different dimensions of trust are mutually reinforcing, from the top of the pyramid to the bottom and vice versa. We, furthermore, need to highlight that nowadays risk communicators operate in the post-trust era, which means that the highest dimension of the pyramid presupposes a general climate of distrust and scepticism. Renn and Levine (1991), however, point out that it is beyond the scope of possibilities, and thus also not the task of risk communicators to affect this climate. Therefore, they have to accept that the negative macro-sociological context negatively impacts on the lower dimensions of trust, which in turn makes them harder to achieve. The only way forward in this situation is to focus very strongly on the lowest dimension of the pyramid in order to consistently work against the negative effect of the highest dimension and to eventually attain the status of a credible institution. In light of this, risk communicators need to understand how to build trust with risk communication messages and this in turn requires a clear understanding of the determining components of trust.

After having thoroughly studied the works of several reputable trust and risk communication authors (Renn & Levine, 1991; Kasperson et al., 1992; Covello, 1992; Peters et al., 1997; Löfstedt, 2005), we have found what appear to be consistent overlaps between the different (selected) accounts. We propose to use the determinants offered by Renn and Levine as it is, in our view, the most comprehensive and complete framework and it, moreover, relates directly to trust in risk communication. The determinants inherent in this account are graphically depicted in Figure 2.

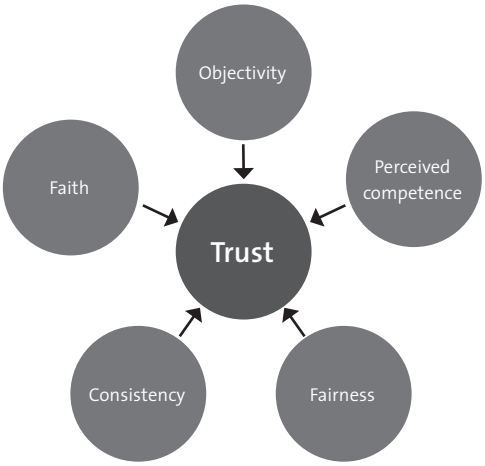

Figure 2 Determinants of Trust. (Adapted from Renn & Levine, 1991)

Renn and Levine further elucidate the five proposed determinants of trust:

- Competence is equated with perceived "technical expertise".
- Objectivity is the perceived lack of information bias.
- Fairness is given if all relevant points of view are adequately represented and acknowledged.
- Consistency is provided if the arguments and behaviour of the communicator are predictable on account of past communications.
- Faith is attributed to the communication source if the receiver perceives of "good wil " in providing the risk communication (p. 179-80).

Renn and Levine have proposed these five determinants of trust in risk communication without explicitly having a particular type of risk communicator in mind. These five

determinants therefore represent a rather general set of determinants of trust, which do not incorporate specific particularities of certain communicators. In light of this, we argue that the perceived particularities of communicators, such as the allocated role or position in society, have at least some impact on the qualities expected from the communicator for him to be trusted. A regulator, for instance, has arguably a different role, and thus also agenda, in society than a private company. In short, the relevant determinants of trust might differ from one type of communicator to the other. This paper focuses on business as the risk communicator. While we deem consistency, fairness, and competence[9] to be relevant and suitable determinants of trust for business as well, we question the applicability of objectivity and faith. We by no means posit that it is impossible for business to earn a reputation for being reasonably objective and good-willed. We rather doubt that it has a significant impact on trust if business fails to be perceived as objective or if it fails to be seen as "good-wil ed" (cf. definition of faith). In other words, we question the relevance of objectivity and faith as constituent factors of trust in business as a risk communicator.

The issue with both objectivity and faith relates to the widely held stereotype that business' main interest is the maximisation of profits (Peters et al., 1996). Taking this perception into account, is it then really expected from business that they are objective, that is, without bias in their risk communications? Moreover, does it mean that business loses public trust if it is not perceived as pursuing "good wil " in their risk communication? Or is it, maybe, something else, which is expected of business for it to earn the trust of their stakeholders?

Starting with objectivity, it lies in the very nature of business that they pursue a vested interest: they *want* to convey the safety, and not the potential hazards, of their products in order to sell it to trusting customers. It is arguably not in their interest, *per se*, to give an objective account of the risks regarding their products. Of course, they do not want to sell toxic junk to their customers, as they would then put their reputation at risk (Regester & Larkin, 2005). If possible, business will try to minimise potential hazards of their products so that there is less objective reason to question the safety of them. However, in a product field with a lot of uncertain risks such as that of GM food products, it is impossible to reduce these uncertain risks to negligibility. Therefore, risk communication becomes all the more important. The GM food producer is very likely to be optimistic about these

9 Consistency, fairness, and competence crucially depend on the case at hand and thus have to be evaluated on a case-by-case basis. For competence (or correspondingly expertise), however, we are informed by past empirical research that industry in general scores fairly high (Peters et al., 1996).

uncertain risks as wel as potential benefits (if not, the company's *raison d'être* would be severely hampered) and is also interested in conveying its subjective optimism to outsiders. Hence, it is in the interest of the GMO producer to understate the salience of these uncertain risks and to emphasise the potential benefits instead. Hence, its account is necessarily subjective, that is biased towards positive information.

With a view to faith, GMO producers do not pursue, *per se*, "good wil " when they communicate product risks. Again, they clearly have a vested interest, which is private. The public will not be naive about this. On the contrary, as Terwel et al. (2009) show for the case of companies involved in the storage of carbon dioxide, if business pretends that it does not have commercial interests it will negatively affect public trust in it. It simply would not be credible. However, as Regester and Larkin (2005) note, "there is a growing expectation [among stakeholders] that organisations should perform and behave in a more open, socially caring and responsible way" (p. 16). Corporate social responsibility necessitates that business, instead of focusing on internal objectives only, also needs to incorporate bigger societal values and public demands into its decision-making, what Regester and Larkin (2005) cal "outside-in thinking" (ibid.). Consequently, some good will on the part of business is, indeed, more and more expected in today's complex societies. However, as Regester and Larkin further point out, rather than conveying faith (i.e. perceived genuine good will) business needs to show that they are accountable to the concerns of their stakeholders.

The difference between accountability and faith is, indeed, evasive looking at the outcome in terms of the behaviour or action warranted on part of business. The difference lies in the motivations for these actions. While faith presupposes that deeds are, *per se*, done out of a genuine goodwill, accountability implies that the actor behaves in a way that accommodates the concerns and interests of stakeholders because he faces a sanction if he fails to do so. In our view, the latter is a more appropriate description of what motivates business to "outside-in thinking" or corporate social responsibility. The sanction for business for not behaving in this manner is loss of reputation, and consequently loss of the "tacit acceptance of society to continue to operate" (Regester & Larkin, 2005, p. 16). In conclusion, we deem objectivity and faith to be less appropriate determinants of trust in business. However, in scenarios where private actors have no genuine motivations, *per se*, to be objective and care for the concerns of those affected by their actions, it is still possible to hold these private actors accountable for the consequences of their actions. It is in this context that we wonder if accountability might substitute for objectivity and faith as a determinant of trust for business when it assumes the role of a risk communicator. We accordingly position the following first preliminary hypothesis: *Accountability is a constituent factor for trust in business*. If this holds true, business should pursue a strategy

aimed at proactively rebuilding trust through establishing a perception of accountability. In light of this, we need to proceed by acquiring an understanding of accountability and its constituent factors and link it to the realm of risk communication.

Accountability and Risk Communication

In order to conceptualise accountability, we, in parallel with the work of Drott et al. (2012), build upon the accountability conceptualisation by Bovens (2007). In more detail, Bovens (2007) frames accountability as an account-giving relationship and outlines seven interrelated conditions, which all need to hold for overal accountability to exist: "(1) there has to be a relation between an actor and a forum, (2) where the actor is obliged to inform about, (3) explain and justify his conduct to the forum, (4) so that the forum can interrogate the actor, (5) question the legitimacy of his conduct (6) and pass judgment on the actor's conduct (7) which might lead to sanctions of some kind" (p. 10). At this point, however, we have to highlight that Bovens designed this conceptualisation with a political and/or regulatory environment in mind (Joss 2001; Drott et al., 2012). Correspondingly, in the ensuing subsections some of the conditions are altered to better match them to the field of risk communication.

The focus on risk communication in this context is warranted, as business needs a vehicle of how to convey a perception of accountability. Especially in the context of today's post-trust era, in which there exists uncertainty about the risks inherent in GM food products, risk communication becomes ever more important for business. Given this situation, how does effective risk communication look like? More specifically, how must risk communication be designed when one aims to rebuild or maintain trust? Linked to our preliminary hypothesis set out above - *accountability is a constituent factor for trust in business* - we now propose to build a synthesis between the concept of accountability and some streams in risk communication. In other words, we adopt the preliminary hypothesis to the realm of risk communication. In light of this, we argue that despite the necessity for some very minor phrasing and content adjustments, Bovens' accountability conditions have a substantial overlap with some recurrent themes in the field of risk communication. To further specify this overlap, we conducted a thorough literature review (Fischhoff, 1995; Leiss, 1996; NRC, 1996; Löfstedt, 2004; Löfstedt, 2005; World Health Organisation, 2005; Jung, 2006; Löfstedt, 2006; Risk Regulation Advisory Council, 2009; International Risk Governance Council, 2005; Sellnow, 2009; Bouder, 2010; Smillie & Blissett, 2010), and in the process identified what we believe to be three central themes for requirements of 'effective' risk communication in the post-trust era: *inclusiveness*, *responsiveness* and *transparency*. To better il ustrate the overlap of Bovens' accountability conceptualisation with these

themes in risk communication, we proceed by breaking down Bovens' conceptualisation into its seven constituent conditions and allocating them to the respective theme in the risk communication literature.[10]

Inclusiveness

The first central theme that we have discovered is best captured by the term 'inclusiveness'. We equate inclusiveness in risk communication to the inclusion of stakeholders, offering them the opportunity to voice their concerns and questions. It describes a process, in which the communicator proactively creates venues for stakeholder input and/or listens to their concerns. One could refer to this process as stakeholder participation or deliberation, an issue dealt with widely in the literature (e.g. Leiss, 2001; Löfstedt, 2004; Löfstedt 2006; Smillie & Blissett, 2010).[11] It needs to be clarified that inclusiveness only describes the degree of participation, which is needed for the communicator to draft his message in the most effective way. It has the aim of "understanding [...] the target audience" (Jung, 2006, p. 820) in order to deliver a suitable message. Fischhoff (1995) refers to a necessity of treating the recipient nicely and, moreover, making him a partner (p. 142), which describes a process of actively accommodating him and including him in the process (cf. Leiss, 1996). Inclusive risk communication today is a part of the best-practice for governmental risk regulators (Risk Regulation Advisory Council, 2009), but also forms part of best-practice suggestions for business (Smillie & Blissett, 2010).

Moreover, this theme appears to be represented in what Bovens found to be the first criterion for accountability: 1) there has to be a relation between an accountor (actor) and an account-holder (forum).[12] While this is clearly the most basic requirement for an interaction to take place, we further argue that also Bovens' fourth condition can be al ocated here: (4) the account-holder can interrogate the accountor. However, we deem it more appropriate to rephrase the statement to saying (4) the account-holder can ask

10 As previously already announced, we, in the process, also argue in favour of adjusting the phrasing of some of the seven constituent conditions to better match them to our non-institutional application.

11 Löfstedt discusses the desirability of stakeholder participation (2004). Yet, in this context we are to draw a general connection between the concepts of risk communication and the accountability concept. Therefore, we are not engaging in a normative theoretical discussion at this point. The same logic applies for our risk communication discussions below.

12 Willems (2010) highlights that Bovens' use of the terms 'actor' and 'forum' in the context of P -A theory lacks clarity and instead advocates in favor of Mulgan's (2000) accountor and account-holder terminology. Therefore, actor is henceforth replaced by accountor and forum is replaced by account-holder. In the context of risk communication, the risk communicator represents the accountor and the public stakeholders the account-holder respectively.

questions to the accountor. The underlying rationale is that we do not believe there to be many cases, in which a stakeholder can actually interrogate a company regarding its conduct. However, the possibility to pose questions, especially those focusing on comprehension issues, is a requirement for inclusiveness (Fischhoff, 1995; Sellnow, 2009).

Transparency

The second theme, 'transparency', may appear to seamlessly overlap with inclusiveness. We nevertheless argue in favour of including transparency as a stand-alone theme. It describes the adequate and open provision of information to the recipients by a communicator. Fischhoff (1995) already described the evolution of transparency from a mere delivery of raw information to an explanation of the data, and, finally, also the presentation of a comparison of present risks to past or already familiar risks. It follows from this that transparency in risk communication is not merely a gesture to open up the process of risk communication to public scrutiny, but a proactive task of explaining and justifying the communicator's conduct within the process. That is what we referred to as *adequate* provision of information above. Löfstedt (2006) states that by "placing deliberations on the internet, making actual correspondence ... publicly available, and encouraging scientists to participate" (p. 876) transparency can be ensured. Sel now (2009) circumscribes the same thinking with 'accessibility'. In this context, he highlights that if risk communication is hard to grasp for laymen, communicators ought to simplify the message.

The essence of transparency set out above appears inherent in Bovens' second criterion (2), which prescribes an obligation on the side of the accountor to provide information to the account- holder. In our context, *obligation* should not be read too literally. Rather than being (legally) proscribed to do so,[13] business will provide information voluntarily because it wants to serve the perceived public demand for transparency. Moreover, Bovens' third condition (i.e. the accountor explains and justifies his conduct to the account-holder) aligns with what we referred to as adequate provision of information.

Responsiveness

Our third theme, 'responsiveness', also firstly needs to be distinguished from inclusiveness. Inclusiveness means that the communicator accommodates his stakeholders and listens

13 Admittedly, cases exist, where regulation obliges communicators to provide information - e.g. risk assessments and labelling requirements - but this cannot be generalised for every risk communication act of a GMO producer. In the context of our transparency conceptualisation, we therefore argue in favour of dropping the obligation aspect, so that information provision for business is largely voluntary.

to their concerns. Responsiveness, further, means that the communicator acts upon them. Hence, responsiveness presupposes inclusiveness. We thus refer to *responsiveness as the ability of the communicator to respond to his stakeholders' concerns and feedback as well as to actively forge and steer the debate surrounding the risk issues*. This need for active engagement with stakeholders has developed as an unavoidable consequence of the post-trust era. In a society where the communicator's conduct is closely scrutinised, a disengaging demeanour quickly creates an impression of lacking concern and care, especially for business (Sellnow, 2009). Therefore, business has to respond to voices from the public in order to be perceived as fully engaged and to be taking issues seriously. Löfstedt (2005) and Löfstedt et al. (2011) point out that it is more beneficial for communicator's level of trust to proactively engage with the public than to be a passive object of their evaluation.[14] Fischhoff (1995) and the NRC (1996) go as far as to state that reactive risk communication creates distrust. Today, it is widely acknowledged that responsiveness - in the literature often referred to as 'two-way communication' - is central to nourishing trust relationships (Löfstedt, 2005; Bouder, 2010).

Certain conditions have to hold for the communicator to be responsive to the concerns of stakeholders. It appears that these conditions correspond to Boven's fifth to seventh condition for accountability. For accountability, (5) the account-holder has to have the right to question (the legitimacy of) the accountor's conduct. Bovens originally refers to legitimacy (here put in parentheses), a recurrent theme in the political/regulatory domain but less so in business. As our focus is on business, we decided to avoid this concept. Upon questioning the accountor's conduct, (6) the account-holder must further be allowed to pass judgment on the conduct in question. In the context of risk communication, the ability of stakeholders to question and judge the communicator's conduct are necessary inducements for the communicator to be responsive to the stakeholders' concerns as well. However, these inducements would not be effective if judgments (positive or negative) are not (7) followed by sanctions (also positive or negative) of some kind. In the context of risk communication and our focus on business, the sanction could be, for instance, the awarding of more trust to the communicator or, in case of negative judgment, distrust.

To summarise, this section has conceptually related accountability with our three central themes for effective risk communication. This synthesis can be seen in the following Table 1, which groups Boven's seven conditions under the headings of the three themes.

14 Focusing on the regulator, Löfstedt et al. (2011) state that only a proactive risk communication strategy can break the "vicious circle of risk aversion" (Bouder, 2008, p. 47). As the aim of this intervention is also to establish trust, we deem it appropriate for the risk-producer too.

Inclusiveness	Transparency	Responsiveness
• (1) there has to be a relation between an accountor and an account-holder • (4) the account-holder can ask questions to the accountor	• (2) the accountor informs about • (3) explains and justifies his conduct to the account-holder	• (5) the account-holder can question the accountor's conduct • (6) and pass judgment on the actor's conduct • (7) which might lead to sanctions of some kind

Table 1 Accountability in Risk Communication. (Adapted from Bovens, 2007)

In derivation from this synthesis, we suggest that

- If business *includes* all relevant stakeholders in the process of risk communication and actively listens to their concerns and points of view;
- and is *transparent* in the process in that it informs stakeholders about its conduct, and moreover explains and justifies it;
- and *responds* timely and appropriately to the voiced concerns, showing that it takes them seriously and acts upon them;
- then the risk communication conveys the *accountability* of the communicator.

Correspondingly, we shall refer to risk communication, which fulfils all three themes as *accountable risk communication*. Next, we argue why, according to our central hypothesis, accountable risk communication is trust-building risk communication.

'Accountable Risk Communication' is Trust-Building Risk Communication

There are several reasons why accountability, conveyed by an appropriately designed risk communication – *accountable risk communication* – might build trust in the risk communicator as well as the conveyed message. In this, it might compensate for objectivity and faith, which, as argued before, are less appropriate determinants of trust in business.

For a start, we have previously argued that the public does not expect business to be objective or to pursue a "good will" per se. The public correspondingly also knows that business has a subjective interest and is rather concerned with profits than with the provision of public goods. However, subjectivity and profit motive must not mean that business cannot be trusted. In short, objectivity and faith are not, it is argued, necessary determinants of trust. Accountability, by contrast, is not in conflict with business profit-maximising interest. On the contrary, displays of accountability on part of business serves its profit motive in that it prevents negative sanctions (or enables positive sanctions) that impact its profitability. For example, earning a positive reputation of

trust (positive sanction) on part of its customers or the regulator may lead to increased sales or a lightened regulatory burden respectively. Both would increase profits. Without accountability, however, stakeholders have no assurance that their concerns and points of view are taken into account. This will reduce the trust they assign business.

Also when looking at the three selected constituent themes of accountability one-by-one, one can discern in how far accountable risk communication helps in building trust. For instance, if business is open about its interests (transparency), stakeholders have less room for speculation about improper motives. If business is transparent in its risk reports, stakeholders have less reason to speculate about incompleteness and information bias. Moreover, by involving stakeholders more into various processes, business can deflect some criticism, that is, responsibility becomes shared between all involved actors. Then, if business responds to stakeholders' interests and concerns, they can show that they are genuinely concerned about their needs, which in turn helps to build a closer and mutually beneficial and trusting relationship. Generally, if accountability is perceived to be high, the impact of scandals might be reduced because mistakes could be seen as genuine mistakes, and not as the result of improper motives and/or greed.

Based on the above reasons, we arrive at our central hypothesis that *accountable risk communication can potentially help GMO producers in building a trust relationship with the public*. In this logic, accountability is therefore considered to one of the most crucial assets at the disposal of business if it aims to build trust through risk communication. Figure 3 illustrates this relationship of accountability, the three themes of risk communication, and trust in business.

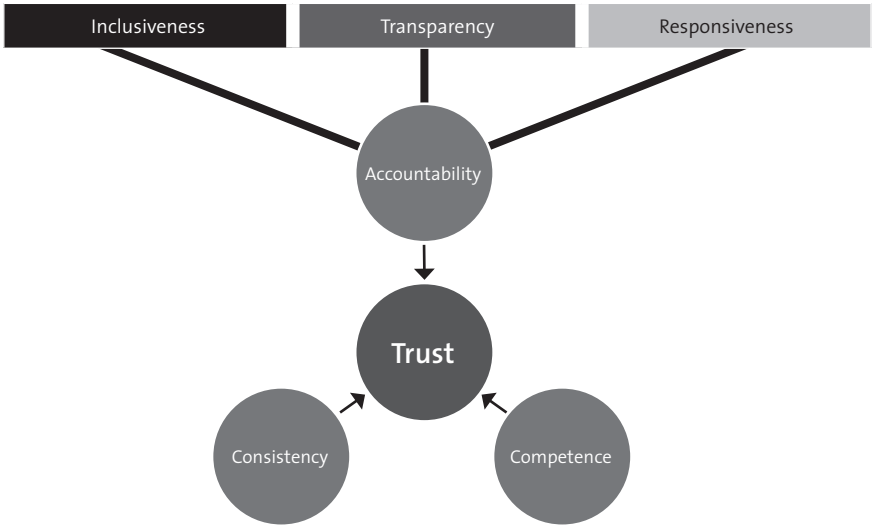

Figure 3 Relationship of Accountability, Risk Communication, and Trust in Business

In this model, objectivity and faith have been replaced by accountability. Moreover, fairness (which does not show up in Figure 3) was not taken into focus as a pressing problem for business. In fact, a perception of fairness in risk communication - acknowledgement and inclusion of all relevant points of view - might still be achieved by business. We do not argue either that fairness is not a relevant determinant of trust in business. However, there are large overlaps with our proposed determinant of accountability, in particular with inclusiveness. In order to avoid redundancies, fairness will be implied by accountability (in particular inclusiveness). Consequently, we are left with competence, consistency, and accountability as the three principal determinants of trust in business.

If one, however, would like to use the above deduced results to assess the practice of a risk communicator, one would firstly have to further operationalise the concept of *accountable risk communication*. Therefore, we deem it useful to further relate the *accountable risk communication* concept to examples of risk communication practices. This will be done within the following methodology section.

3. Methodology

In order to answer our research question of *how GMO producers can communicate their products risks so as to re-gain the trust of the public in today's post-trust era*, we initially set out on a systematic literature review of the concept of trust as well as the studies of risk communication. After an analysis of the determinants of trust, we encountered a potential link between trust in risk communication and the concept of accountability. Therefore, we determined as our preliminary hypothesis that *business can potentially establish a trust relationship with the public through accountable conduct* . Building on this, we incorporated risk communication in our approach and formulated as second hypothesis that *risk communication is a suitable means for illustrating an actor's accountable conduct and thus can potentially help in establishing trust*. In light of the links between the three concepts, we in the next step argued in favour of synthesising them into one theoretical framework. Correspondingly, we also merged the two previous hypotheses into one central hypothesis: *accountable risk communication can potentially help business in building a trust relationship with the public.*

In this context, we, however, also have to highlight a substantial limitation of our research. While we were capable of conceptually arguing in favour of synthesising trust, accountability and risk communication into one framework, we are unable to directly and empirically validate the causal links inherent in the central hypothesis (i.e. in the

two preliminary hypotheses). This limitation, in turn, also has substantial implications for our case study design. Given that we cannot validate the causal links, we can only investigate whether our prescribed model can be applied to analysing real life cases of risk communication and, more importantly, whether there appears to be a correlation between accountable risk communication and certain levels of trust. To this end, we firstly, however, need to bring our framework closer to practice by interlinking it to actual risk communication practices.

With this goal in mind, we related our framework to a number of best-practice-models of risk communication. From the outset, we have to emphasise that one has to be very cautious in generalising findings on risk communication (best) practices. In risk communication, although the evolution of risk communication increasingly moves towards "prescriptive guidelines and principles [for] real life situations" (Bouder, 2010, p. 276), there stil does not exist a comprehensive best-practice model or framework as 'effective' risk communication depends on specific situational factors (Löfstedt, 2004; Löfstedt, 2005; Löfstedt, 2006; Bouder, 2010). Consequently, when trying to evaluate business conduct in terms of transparency, responsiveness and inclusiveness, we have to take into account "contextual factors and situational variables" (Löfstedt, 2005; Sel now, 2009, p. 20). These factors concern the character of the risk communicator in question, the issue he is communicating, the level of certainty involved, the structure of the audience, and the general social climate (cf. Smillie & Blissett, 2010). In very simple terms, it has to be assessed "who is communicating what to whom" under what circumstances, in order to arrive at a tool, which Leiss (1996) referred to as a "code of good risk communication practice" (p. 94). This is to say that specific situational variables appear to be of key importance in creating such a code.

In spite of all this, we deem a practical test of our theoretical results in form of a case study beneficial because it allows us, for a start, to see if our theoretical framework is applicable to real-life acts of risk communication. To this end, we outlined two cases of risk communication by Monsanto Company (hereafter referred to as Monsanto) in an ex-post analysis. We believe our choice to focus exclusively on Monsanto to be warranted, as the company is one of the largest GM food producers in the world. More specifically, Monsanto has a 90 percent global market share in GM seeds, which has made the name company name almost synonymous with GMOs (Haerlin & Busse, 2009; Vector Strategy Group, 2010). Given its role as a figurehead of the GMO producing industry, Monsanto, moreover, is confronted with strong distrust from the public, as evidenced by numerous anti-Monsanto interest groups, websites and demonstrations (Buffin & Jewell, 2001; Ho & Cummins, 2005; Sueddeutsche, 2009; McMahon, 2011; Adams, 2011).

Based on these circumstances, we can delineate a specific situation: Monsanto, a GMO producer, is communicating the risks of its products to the public at large (including direct customers, final consumers, scientists, interest groups and the regulator). The impacts of Monsanto's products on the environment as well as human and animal health are still disputed and thus uncertain. It can, moreover, be stated that the general climate towards both the company and its products is characterised by a low degree of trust.

Who?	Monsanto - GMO producer (business)
What?	Product risks and safety (GMOs; herbicides)
To whom?	Customers, consumers (incl. consumer groups), regulator, interest groups (heterogeneous group)
Certainty?	Uncertain
Social Climate?	No trust (post-trust era)

Table 2 Monsanto's Effective Risk Communication Strategy

Given this situation, how could Monsanto's effective risk communication strategy look like? Löfstedt (2005) states that "industry should 'test for trust' and, if distrusted, uncover why and act appropriately" (p. 11). Correspondingly, Monsanto's risk communication, thus, needed to tackle the origin of the distrust towards them. In this regard, Peters et al. (1997) state that "industry, according to a common stereotype, is commonly perceived to care and be concerned only about profits, and minimally about public health and safety" (p. 54). Moreover, their findings suggest that fighting this "negative stereotype" is often the most successful strategy to build trust. With a view to Monsanto, this task, however, is complicated by the uncertainty regarding GM food products and the heterogeneity of its audience. Before we move on to the case study, we further specify 'accountable risk communication' into concrete guidelines which also serve as check boxes of our following evaluation tool.

Transparent Risk Communication

A crucial factor adding to the distrust towards the GM food industry in general is the uncertainty surrounding GMOs, especially with regard to possible long-term risks. In situations involving high uncertainty, transparency in risk communication is required (Fischhoff, 1995). Transparency in this context also requires honesty about the unresolved uncertainties. This is to say that Monsanto should refrain from neglecting or even covering up scientific uncertainty about risks. Due to this uncertainty, risk assessments simply

cannot be unequivocal and, therefore, a top-down message will always appear weak if it tries to claim the contrary (i.e. complete certainty about risks, or worse, unequivocal safety). The advised strategy in this case is, therefore, to be transparent about one's results. Whilst the drafted message should thus admit the lack of certainty, it should also contain an element of assurance. In this regard, Sel now (2009) coins phrases such as "[w]e do not yet have al the facts" or "[o]ur understanding of these factors is always improving", which are easily understandable and transmit insecurity as well as assurance at the same time (p. 23; cf. Fischhoff, 1995). Moreover, Monsanto should desist from concealing their interests and delivering messages in an overly praising tone. Instead, Monsanto should also communicate potential negative aspects and counter-positions so as to illustrate the entire picture and not only potentially misleading pieces of it (McGuire, 1985; Lee, 1986; Renn and Levine, 1991; Sellnow, 2009). Finally, apart from merely providing scientific data, Monsanto should also ensure the accessibility of this data in terms of understandability, by addressing different stakeholders with an adequate level of scientific complexity. This is to say that specific recipient groups have to be addressed with specific messages, without substantially altering their content (Sellnow, 2009). In order to create this message, feedback concerning understanding problems has to be incorporated and messages adapted accordingly (ibid.).[15]

Responsive Risk Communication

Löfstedt (2005) argues that in situations of high trust, deliberative strategies can lead to distrust. However, in today's post-trust era, the overarching problem facing Monsanto is the high degree of *dis*trust in the wider societal climate. In this climate, proactive deliberation, or two-way communication, is advisable (ibid, p. 125; cf. NRC, 1996) because only this way Monsanto can discern and target concerns of the public, that lead to distrust, directly and effectively. For this, Monsanto should listen and incorporate all the feedback it can acquire through the deliberation process. This is to say Monsanto should engage in a true two-way communication process. Moreover, within this dialogue, Monsanto should also ensure the timeliness and the quality of its response. Stakeholders will feel that Monsanto does not take their concerns seriously if it lets too much time pass until it responds (cf. World Health Organization, 2005). The same rationale holds for the quality of the response. More specifically, the response should result from a comprehensive engagement with

15 A negative example for this situation can be found in the Brent Spar case, where Löfstedt (2005) found that a strategy of not deliberating with the public led to unintended results in a situation where there was distrust and scientific uncertainty.

stakeholders in which Monsanto processes the input from stakeholders (Regester and Larkin, 2005). Renn and Levine (1991) even go further stating that insights gained from this deliberation actually have to be transposed into a correction at the source. The deliberative process can in fact help to "change public expectations or to correct misperceptions [...], but it wil not cover the gaps between expectations and perceived performance" (p. 197).[16]

Inclusive Risk Communication

Monsanto is also confronted with the problem of a heterogeneous audience. Several distinct stakeholders are interested in Monsanto's risk communication, including customers (mainly farmers), final consumers (at retail level), scientists, interest groups (e.g. consumer groups or environmentalists), the regulator, the media and in all likelihood also further stakeholders. This heterogeneous group naturally also has a wide range of distinct interests, points of view, and concerns, which in turn means that Monsanto cannot simply draft one single message that has the same desired effect on every stakeholder (Smillie and Blissett, 2010). In order to deal with this heterogeneity, Monsanto has to include stakeholders in the process preceding the risk communication so as to learn what they care about and what their points of view are.[17] In this way, misunderstandings and communication problems can be remedied more directly and flexibly. To reach this goal, Monsanto must create venues for risk- stakeholders to express themselves (Sellnow, 2009). Ideally, Monsanto should adopt ways to create sympathies (cf. Renn & Levine, 1991) so as to forge a relationship with its stakeholders as partners, rather than just recipients of top-down messages. Finally, Monsanto should try to convey a perception of inclusiveness that shows concern and care towards its stakeholders (cf. Peters et al., 1997).

In sum, the three criteria of accountable risk communication - inclusiveness, transparency, and responsiveness - can be translated in very concrete guidelines of how to design the risk communication process. It depends on situational variables which of the three criteria must be checked. In the case of Monsanto, the situational variables (heterogeneity of audience, uncertainty around risks, climate of distrust) warrant adoption of all three criteria. Figure 4 provides a concise overview over the required qualities for accountable risk communication. It groups Boven's seven conditions for accountability under the three themes of inclusiveness, transparency, and responsiveness, and translates them into concrete guidelines. It is intended to be used as an evaluation tool to assess the

16 A best-practice example can be found in the CXY Chemicals case (Leiss, 1996).

17 The specific context hereby seems to give an answer on whether stakeholder participation is beneficial or not - a controversy studied by Löfstedt (2004; 2005).

accountability of risk communication of GM food producers. In the following case study, we apply it to two cases involving Monsanto as risk communicator.

Heterogeneous audience	Uncertain risks	Post-trust climate
• (1) there has to be a relation between an accountor and an account-holder • (4) the account-holder can ask questions to the accountor	• (2) the accountor informs about • (3) explains and justifies his conduct to the account-holder	• (5) the account-holder can question the accountor's conduct • (6) and pass judgment on the actor's conduct • (7) which might lead to sanctions of some kind
• Give risk-stakeholders opportunity to express their concerns • Show concern and care for stakeholders • Create sympathies	• Show opennes and honesty about motives & interests • Ensure accessibility of information • Explain with an adequate sense of audience • Do not appear overly certain (i.e. acknowledge uncertainties) • Communicate pro & con, instead of merely positive aspects	• Search proactively for a dialogue • Enable two-way communication (listen & respond) • Ensure timeliness and quality of responses • Correct wrongs (e.g. bad management)

Figure 4 Accountable Risk Communication Framework

In light of the highly contested nature of GMOs, we put great emphasis on conducting research in an unbiased manner. While we are aware that such research is virtually impossible, we nonetheless tried to apply triangulation to both lessen the effects of biases and in order to crossvalidate our findings using different sources as well as methods. More specifically, we predominantly conducted qualitative research and therefore relied heavily on desktop research, document analysis and primary sources from both Monsanto and (independent) scientists. With a view to triangulation, we also contacted Monsanto itself as well as a number of relevant stakeholders asking them for an interview and additional information. However, no party agreed to provide us with any additional information or to give us an interview (free of charge).

4. Case Study

Introduction to Monsanto

The purpose of this section is to empirically test whether the risk communication of Monsanto is accountable in order to, then, ideally gain an insight into whether there is a correlation between accountable risk communication and building trust. With this goal in mind, the first case revolves around Monsanto's Roundup business model. This model is based on a bundling of so-called Roundup Ready GM crops and the Roundup herbicide, whose active ingredient is glyphosate (Monsanto, 2012). The rationale underlying this bundling is that the glyphosate-based herbicide systemically and non- selectively destroys all plants in its application area (ibid.). At the same time, however, the Roundup Ready crops have been genetically engineered so as to be resistant to glyphosate, which thus renders the two products compatible (ibid.). This means that in practice, farmers, upon planting Roundup Ready crops, can broadly apply the Roundup herbicide to destroy all unwanted weeds, whilst leaving the Roundup Ready crops unharmed.[18]

In recent years Monsanto has further enhanced this business model by incorporating additional DNA-sequences into the Roundup Ready crops, which are designed to increase the plants' yields as well as their resistance to certain insects and extreme weather conditions (ibid.). These advances, thus, also fal in line with Monsanto's corporate goals for sustainable agriculture, which are centred around "producing more,[19] conserving more,[20] improving lives[21]" (ibid.). In Europe and elsewhere, despite these socio-economically beneficial goals, however, one can observe strong opposition to Monsanto as wel as to their GMOs and herbicides, as Monsanto is widely claimed to be "evil" and its products to be potentially dangerous (Whitman, 2000; Regester & Larkin, 2005; Sueddeutsche, 2009; McMahon, 2011). Especially in this context, it should therefore be in the interest of Monsanto to focus on establishing a trust relationship with the public. In light of the fact that Monsanto's primary business model is based on both herbicides as wel as GM crops, we argue that Monsanto's risk communication pertaining to either of the two products should have repercussions for

18 The novelty inherent in this model is that in the past not only more but also different types of herbicide had to be used to achieve the same result.

19 It is Monsanto's goal to double yields in its core crops by 2030 (Monsanto, 2012).

20 This doubling shall, moreover, occur with the use of one third fewer resources such as land, water and energy per unit (ibid.).

21 By increasing both yields and productivity, Monsanto also aims to raise farmers and "many more people" from poverty to prosperity (ibid.).

Monsanto as one entity. This is to say that if Monsanto manages to build trust in one certain business area, this perceived trust would also spill over to other business areas it operates in. The same spillover effect, however, would also hold true for distrust. Given this situation, we proceed by analysing two instances of Monsanto's risk communication with the aim of evaluating whether said risk communication has been done in an accountable way and thus potentially could have led to trust.

Monsanto's Roundup Advertising

In the 1990s, Monsanto introduced a refined version of its Roundup pesticide product and correspondingly advertised for it through various broadcasting and print media channels both in the US as well as in the EU. These advertising campaigns were all aimed at highlighting the benefits of the new herbicide: "[t]*his is Roundup, the first biodegradable herbicide. It destroys weeds from the inside, down to the roots, while leaving [...] the soil [...] pollution free". Or "Roundup can be used where kids and pets'll play"* (Monsanto, 1996). Other claims of the same marketing campaign include it is "safer than mowing" and it is "environmentally friendly" (ibid). A close reading of these advertising claims illustrate that Monsanto put great emphasis on differentiating its new product on the basis of its alleged safety, as there appear to be no adverse effects to the environment, humans and animals. While advertising campaigns usually do not fall under the category of risk communication, we believe that given the nature of this marketing campaign, it can, in this instance, be argued that Monsanto engaged in direct risk communication to potential consumers. In line with the purpose of this section, we therefore proceed by analysing whether Monsanto's risk communication has been transparent, responsive and inclusive.

With a view to transparency, it is important to evaluate whether Monsanto not only informed consumers about the benefits of its new product, but also *explained* and *justified* its claims. In this respect one has to highlight that the new product was a herbicide, that is, a product aimed at *poisoning* plants. While the active ingredient in Roundup, glyphosate, is primarily toxic to plants, it is nonetheless to some degree also toxic to humans, animals and the environment. Correspondingly, a number of scientific reports testify that even small amounts of glyphosate are *highly* toxic to humans, animals and can have adverse long-term effects on the environment (Buffin & Jewell, 2001, p. 7; Bellé, 2001; European Commission, 2002; Engdahl, 2010). In light of these scientific findings, one can thus argue that Monsanto failed to explain and justify its advertising claims in a fair and open manner. Especially, the claim that Roundup "can be used where kids and pets'l play" creates a false sense of security for parents and is thus very questionable.

It is also in this context that Monsanto has been found guilty of false and misleading

advertising in two cases before a court in New York (1996)[22] and numerous instances in France (2007, 2008 and 2009).[23] In the former case, the New York State attorney general sued Monsanto for claiming that its Roundup products were "safer than table salt" and "practically non-toxic" to birds, fish and mammals (Vacco, 1996). Monsanto was ordered to "cease and desist from making any of the specific statements" about the safety of its products (Ruling on the matter of Monsanto Company (1996), pursuant to executive law § 63(15), New York). In the latter case, the French environmental association *Eau et Rivières de Bretagne* had sued Monsanto in 2001 for making false claims about Roundup (BBC, 2009; Le Monde, 2009). In 2007, Monsanto was fined €15.000 by France's criminal court in Lyon[25] for claiming that Roundup is "biodegradable" and that it "leaves the soil clean" (BBC News, 2009), whilst the EU classifies its active ingredient as "dangerous for the environment" (European Commission, 2002) and toxic for aquatic organisms (ibid.; Le Monde, 2009; Huff, 2012). In 2008, the court of appeal in Lyon confirmed this judgement[24] (BBC, 2009, Le Monde, 2009). Yet, although Monsanto appealed the decision, in a final ruling France's Supreme Court (*Cour de Cassation*) decided to reject Monsanto's claims thereby making the fine of €15.000 legally binding[25] (ibid.). It can thus be argued that the misleading information by Monsanto is in itself a central factor why Monsanto's conduct, in this case, cannot be considered transparent. In addition, we can conclude from Monsanto's bold claims, that the company pursued an overly certain and reassuring communication strategy with an unequivocal message. Although we must consider that the object of analysis is a marketing campaign - a type of communication, which per se is designed to be unequivocal - one can nevertheless question why Monsanto focused its advertising on the one characteristic of its product, which was controversial. Instead, Monsanto could have honestly focused on the benefits of their herbicide in conjunction with its own GM crops. However, Monsanto chose to follow a different path, in which it tried to cover a potential weakness behind overly assuring statements.

With a view to responsiveness, we can observe that Monsanto failed to engage in a meaningful two-way communication with the public concerning the claims they have

22 Case (1996): False Advertising by Monsanto Regarding the Safety of Roundup Herbicide (Glyphosate). Attorney General of the State of New York. Assurance of discontinuance pursuant to executive law § 63(15).

23 Case 1 (2007): TC Lyon No 0077764, 26 January 2007 (France Nature Environnement, 2008).
Case 2 (2008): CA Lyon No 1012/07, 29 October 2008 (ibid.).
Case 3 (2009): Ccass No D 08-87.757 F-D No 5358, October 2009 (Eau et Rivieres de Bretagne, 2009).[25]
TC Lyon No 0077764.

24 CA Lyon No 1012/07.

25 Ccass No D 08-87.757 F-D No 5358.

made in their advertising campaign. While we did come across responses from Monsanto, we deem them to be very top-down in nature as well as very time-delayed. With regard to the first claim that Roundup "can be used where kids and pets'l play", Monsanto did not immediately publish supporting scientific data. More precisely, the marketing campaign was launched in 1996 and the first official Monsanto document claiming that Roundup has no adverse effects on children living on a farm, on which Roundup is used, was only published in May 2005 (Monsanto, 1996; Monsanto, 2005). Moreover, as the two previously outlined court cases show, consumer and interest groups already even legally questioned these claims immediately in 1996 in New York and then in 2001 in France. While one could argue that Monsanto's document is based on a scientific study, which was already published in 2000, it would still leave four years in which Monsanto had put forward a claim without having any kind of supporting scientific data to engage in a fruitful and sincere public discussion (Williams et al., 2000, in Monsanto, 2005).

What is more, in this and other documents Monsanto makes no efforts to discuss the claims of other scientific studies, which claim almost the exact opposite to be true with regard to the safety of Roundup (Buffin & Jewell, 2001; European Commission, 2002; Ho & Cummins, 2005; Huff, 2012; EPA, 2012). Furthermore, Monsanto also refrained from transcribing the scientific findings to make them easier to comprehend for consumers but instead only quoted very technical elaborations (Monsanto, 2005). We would, therefore, argue that the quality of the response with regard to Roundup's safety to humans was heavily compromised by a substantial time delay, a lack of real engagement and the very technical nature of the response. Moreover, a similar pattern can be observed with regard to Monsanto's second claim of biodegradability. There, again, was a substantial time delay, as Monsanto only published a document substantiating its biodegradability claim in October 2005. While in this instance, Monsanto succeeds in presenting the results in a relatively easy to comprehend fashion, it again makes no references to the very contested nature of the presented findings, namely, the public debate and the legal court case surrounding these contested claims (Vacco, 1996; Buffin & Jewell, 2001; BBC, 2009; Reuters, 2012). With a view specifically to the French court cases, we can, moreover, state that Monsanto failed to correct a "wrong". After having been sentenced for misleading advertising by the court in Lyon, Monsanto unsuccessfully continued to appeal the decision up until to the French Supreme Court. This behaviour illustrates that Monsanto failed to admit any misconduct on its side and, furthermore, also made no attempts to show any kind of remorse.

With regard to inclusiveness, we can observe that Monsanto adapted a two-fold approach. Given the fact that the risk communication in question is a marketing campaign, it was directed at a relatively wide target group including private households as well as

commercial farmers. At the same time, however, Monsanto appears to have tried to avoid a scientific debate. To this end, Monsanto based itself on as few scientific reports and tests as possible to justify its product-lines and to keep its investments low (Glickman & Rifkin in Robin & Garrel, 2007). These scientific reports were, moreover, predominantly conducted in-house, which allowed Monsanto to keep a close eye on the outcomes as well as the dispersion of the same (ibid.). According to an EPA reviewer this situation culminated in a "routine falsification of data" (Cox, 1995; Margulis, 2009) in test results, which led Sellnow (2009) to exclaim that such behaviour represents a clear denial by Monsanto to include the public (p. 26).

In sum, we thus find that Monsanto did not communicate the product risks of its Roundup herbicide in an accountable manner as neither transparency, responsiveness nor inclusiveness was given. More specifically, we deem the shortcomings in regard to transparency and responsiveness to be very substantial. While this particular instance does not allow us to verify whether our hypothesis is accurate, we can nonetheless conclude that Monsanto did not seem to put much emphasis on communicating product risks in an accountable manner in this case. This in turn potentially might hint at one cause for Monsanto's lack of trust. At the same time we need to highlight that Monsanto itself appears to some extent overconfident with regard to how much public trust it actually enjoys. In response to having been sentenced for misleading advertising pertaining to its Roundup products in France, a Monsanto France spokesperson confidently claimed that "[t]here is a relationship of trust between our products and their users and we believe that consumers will continue to use Roundup" (TerraDaily, 2007). This alleged relationship of trust is very important for Monsanto, as the business model, *inter alia* based on this herbicide, accounts for half of Monsanto's overal revenue (Caval aro, 2009). Interestingly enough, however, in the year between the first ruling and Monsanto's appeal to the higher instance, sales of Roundup herbicide decreased. More specifically, in the fourth quarter of 2008, Monsanto had to post a loss of $233 million, primarily due to lower than expected sales of Roundup (BBC News, 2009). While we do not claim that Monsanto's unaccountable risk communication was the key cause for this decline in sales, we nevertheless want to highlight the possibility that it was a contributing factor and thus may represent a sanction for Monsanto's conduct.

Dr Pusztai's GM Snowdrop Lectin Potatoes

The second instance of risk communication that we like to highlight does not immediately pertain to one specific Monsanto product, but rather the science underlying al of Monsanto's products. In this instance, the British Ministry of Agriculture in 1995

contracted a team of scientists at the Rowett Research Institute of the University of Aberdeen to research the safety of genetically modified food. To this end, the team under the leadership of Dr Pusztai did not test a marketed GMO product, or one intended to be marketed, but instead single-handedly genetically modified a potato to produce an insecticidal protein. In order to then test whether this genetically modified potato could potentially have adverse health effects, the team designed an experiment set-up with three distinct groups of rats. The first test group of rats was fed the genetically engineered potatoes and the first control group was fed natural potatoes. The second control group was fed natural potatoes, which, however, had been laced with the same insecticidal protein that the GM potatoes had been engineered to produce. Ten days into the study Dr Pusztai's team discovered that the group of rats that had been fed the GM potato showed signs of stunted growth and defects in their immune systems.[26] As, however, neither of the two control groups exhibited any of these symptoms, Dr Pusztai and his team concluded that it was not the insecticidal protein that caused these adverse health effects, but rather the generic process of genetic engineering (ibid.; Smith, 2010).

Upon completion of their research in 1998, Dr Pusztai gave an interview to the BBC, outlining his findings and thus informing the British public (Regester & Larkin, 2005). While Dr Pusztai's findings did not concern a particular Monsanto product, it nevertheless questioned the very basis of, the at the time very novel field, of biotechnology and thus also Monsanto's most promising business area (Slovic, 1993). Correspondingly, Monsanto also very actively participated in the debate surrounding biotechnology to illustrate both the safety and the benefits, which it can bring about. However, due to the fact that other scientists expressed their concern about Dr Pusztai's findings, the publishing journal The Lancet repudiated the study for some time (Guardian, 2008; Healthwatch, 1999; Monsanto, 2012). We deem Dr Pusztai's findings to be one part of this debate and therefore also believe it to be of great salience in the context of this section's purpose. In the following we thus proceed by analysing the transparency, responsiveness and inclusiveness of Monsanto's risk communication as part of this debate.

With regard to transparency, we again need to investigate whether Monsanto provided, explained and justified information concerning this case. In this particular instance we can observe that Monsanto generally already puts great emphasis on informing the public about the debate surrounding the safety of genetic engineering as well as about the resulting products. To this end, Monsanto has also established a section

26 The symptoms included smaller brains, livers and testicles, partial atrophy of the liver and damaged immune systems (Rowett, 1998).

on its website where it discusses the general safety of GMOs, the science underlying them, the regulatory food safety requirements, but also the critical claims of Dr Pusztai (Monsanto, 2012). Monsanto does this in a very layman-friendly fashion and with a view to this particular case, also provides an easy to follow summary of the key findings in Dr Pusztai's study (ibid.). This is to say that Monsanto both informs about and explains Dr Pusztai's research. At the same time, however, Monsanto outlines five crucial flaws in Dr Pusztai's research design that, in turn, put the results of the entire research in question.[27] Monsanto justifies this particular act of risk communication by referring to the Lancet and thus basing these elaborations on the work of a highly esteemed scientific journal (ibid.). In addition to this, by relying on the most up-to-date scientific findings and by outlining that Monsanto complies with all regulatory requirements, it, moreover, also makes a strong case for justifying its general conduct (ibid.). In sum, we can thus conclude that in this case of risk communication Monsanto succeeds in fulfilling the transparency criteria.

Moving on to the responsiveness criteria, we argue that in this instance Monsanto did engage in a two-way communication, specifically with Dr Pusztai and through him also with the public at large. The rationale underlying this argument is that we believe Monsanto to be one of the initiators of the debate surrounding the safety of biotechnology, as the company was among the first to market a GM crop in Europe (Europa, 2004). To this end, Monsanto, in line with regulatory food safety requirements, provided evidence on the safety of both the process of genetic engineering and the ensuing products. This information, as outlined in the previous paragraph, was also made readily available to the public. However, after Dr Pusztai had gone public with his findings, which question the truthfulness of this evidence, he was portrayed as a whistleblower and "hero" for protecting the public from potentially very dangerous GMOs (Guardian, 2008). This highly positive portrayal, however, is arguably also based on Dr Pusztai's self-framing as a protector of the public: "I find it's very unfair to use our fel ow citizens as guinea pigs" (ibid).

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27 1. Due to the fact that Dr Pusztai failed to clarify in his study that the GM potato he developed was substantially equivalent to the normal, unmodified test potatoes, any test result is irrelevant. In fact, the possibility is high that the by Dr Pusztai developed GM potato was not substantively equivalent to the non-GM potatoes (Monsanto, 2012).
2. The gen-modified potato used by Dr Pusztai was not a commercially available product and thus not approved for consumption by the government (ibid.).
3. Dr Pusztai inserted a so called "snowdrop lectin", which was obtained from a toxic plant and, moreover, is not a feature of any commercial GMO product. Hence, it was not surprising that he observed changes in the rats, which were fed the GM potatoes (ibid.).
4. The number of rats that had been used in Putsztai's study was too small to get objective research results (ibid.)
5. The diet of the test group and the control groups was not the same, thus the results may potentially be due to nutritional impacts and not toxicity (ibid.)

As having previously already said that GM food was a highly novel phenomenon at the time when Dr Pusztai communicated his findings, the public perception of GM food was ambivalent at best. Given this situation, the GM food producing industry initiated a large advertising campaign in the UK in order to create a greater acceptance for GM foods (ibid.). Dr Pusztai's findings, however, heavily compromised the effectiveness of this advertising campaign and arguably also positioned GMOs in a more negative light. Monsanto therefore had a very strong incentive to engage with Dr Pusztai's claims and thus to show concern and care for the debate. By also outlining Dr Pusztai's position on their website, Monsanto gives voice to critical scientists and therefore does not exclusively focus on communicating positive information regarding biotechnology. As also already outlined in the transparency paragraph, Monsanto's response was of high quality in that it presented Dr Pusztai's claims fairly and openly. The ensuing repudiation by Monsanto was arguably also of high quality, as it is based on the findings of scientists researching for The Lancet. At this point, we, however, have to highlight one limitation in our analysis. As Monsanto fails to provide a date for when it first engaged with Dr Pusztai's findings, we cannot evaluate the timeliness of the response and we thus omit it from our analysis. With a view to responsiveness, we can, in sum, say that Monsanto, given its strong incentive to engage in a debate, succeeded in communicating risks in a responsive fashion.

Continuing onwards to the inclusiveness dimension, we have to highlight that the two preceding conditions already very strongly hinted at the fact that Monsanto generally takes the concerns of scientists and consumer groups seriously. We can thus state that Monsanto actively incorporates critical voices of important risk-stakeholders. Besides, food safety agencies, independent scientists, doctors and consumer organisations are highly important actors for guiding the public debate on whether or not GM food is safe. This argument is based on the fact that, in contrast to GM food producers, the public has strong confidence in these actors (Gaskell et al., 2003). By actively incorporating and even making claims of these groups easily available to the public by featuring them on its website, Monsanto potentially creates sympathies among some stakeholders. This is to say that the inclusive as well as transparent and responsive nature of Monsanto's risk communication in this particular case leaves relatively little room for opponents to criticise Monsanto.

As Monsanto fulfilled all the necessary conditions for accountable risk communication, we would thus argue that this represents a positive example of risk communication on the side of Monsanto. This one act, however, stands in stark contrast to Monsanto's tarnished reputation and its failed attempt in the mid 1990s to expand and establish itself in the European Union (Pearce, 2009). This discrepancy can be best explained with reference to the inverted hierarchical pyramid of trust (Figure 1). More specifically, we argue that one

accountable risk communication act alone is insufficient to seriously affect the (dis)-trust relationship between Monsanto and the public. Any profound positive changes to this relationship would require that Monsanto continuously communicates its products in line with the guidelines inherent in the accountable risk communication framework.

With a view to the larger picture, Monsanto's failure to establish itself in the EU can also be explained by the fact that the company tried to simply copy a functioning business model from the United States' market without paying attention to the local peculiarities of the EU. While NGOs and certain consumers in the United States also voiced their reservations concerning GM food products, these groups largely remained at the fringe of society (Regester & Larkin, 2005). Monsanto correspondingly could refrain from engaging in any serious debates with these stakeholders without experiencing any repercussions. In the EU, however, these critical voices quickly gained the attention of the media and GM food products became a hotly debated topic (ibid). Unfamiliar with this situation, Monsanto neglected the concerns of numerous stakeholders and instead predominantly relied on GMO - friendly governments and regulators to defend its position (ibid). As Europe had largely already progressed into the posttrust era, these institutions, however, were incapable of ensuring the public of the acceptability of GM food product risks. In a further attempt to appease the public, Monsanto thus initiated a $1.5 million marketing campaign in the United Kingdom to convince the public of the safety of its products (ibid). This campaign, however, was very top-down in nature and failed to touch upon the concerns of consumers, supermarket chains, NGOs and other stakeholders.

It was only in 1999 that the Chairman of Monsanto, Bob Shapiro realised the company's shortcoming: "because we thought it was our job to persuade, too often we have forgotten to listen (Regester & Larkin, 2005, p. 57). In sum, we can conclude that while Monsanto in parts appears to have succeeded in communicating the risks of its products in an accountable manner, the overall strategy for entering the European market was flawed. Monsanto failed to realise both the shift in the European societal climate towards the post-trust era as well as the ensuing need to listen and engage with all relevant stakeholders. Our accountable risk communication framework has correspondingly been specifically designed to address both these factors and should thus constitute a relatively powerful tool for businesses in a similar situation to establish a trust relationship with the public.

Conclusion

In this paper, we set out to answer the research question of *how GMO producers can communicate their products risks so as to re-gain the trust of the public in today's post-trust era*. Building on the general conceptualisation of trust in risk communication offered by Renn and Levine (1991), we derived a set of determinants of trust in risk communication for the specific case when a GM food producer is the risk communicator. We argued that, because of its specific role in society, business is not expected to be objective nor to pursue, *per se*, good will in order to be trusted. Instead, we hypothesise that for business, accountability is a determinant of trust. In the context of risk communication, accountability is conveyed by three broad qualities: inclusiveness, transparency, and responsiveness. These three broad themes can be translated into specific prescriptions for business on how to design an accountable risk communication. We suggest that by designing an accountable risk communication process, GM food producers can potentially rebuild trust in today's post-trust era.

The case study on two examples of Monsanto's risk communication has shown that our framework of accountable risk communication can be applied and tested on real life acts of risk communication. According to our evaluations using the framework tool, Monsanto failed to engage in accountable risk communication when it tried to market its Roundup herbicide in Europe and the US with false advertising claims. However, its risk communication concerning GM food in general, in the context of a scientific debate incited by Dr Pusztai, has been largely accountable. While our case study shows the applicability of our theoretical framework, it does not provide empirical evidence, which would validate our central hypothesis that accountable risk communication helps in rebuilding trust. This causal link, however, cannot be established by two cases alone. Moreover, we were unable to find empirical data that could show the impact of Monsanto's risk communications on public trust towards the company. However, Monsanto's bad general reputation as wel as the low acceptability of risks with a view to GM food in Europe correlates with a general poor risk communication performance on part of Monsanto, which epitomises the whole GM food industry (Regester & Larkin, 2005). However, claiming a causal relationship out of this correlation, without further evidence, would be premature. Frewer et al. (1996) provide only mixed evidence. Their findings show that most trust is assigned to communication sources with "moderate degrees of accountability" while those with "too much accountability" are distrusted (p. 208). One confined empirical study alone, especially an outdated one, we argue does not suffice to validate the causal link between accountability in risk communication and trust in the risk communicator.

Even if we assume that *accountable risk communication* does help in building trust, we have to be modest in our expectations concerning the impact of one particular good risk communication. To gain credibility, a company needs to show a continuity of trust-building risk communication. It takes a lot of time and effort to build trust, especially when starting in today's general climate of distrust. Moreover, all the arduously earned trust can be lost in a matter of days due to a scandalised example of bad risk communication. This "fragility of trust" is due to what Slovic (1993) has called the "asymmetry principle" (p. 184), which states that negative (trust-destroying) events "carry much greater weight than positive" (trust-building) events (ibid.).

It is further questionable if trust in the risk communicator is at the root of the problems of the GM food industry. The low acceptability of GM food is certainly also the product of a polarised debate about GM food, which concerns general questions of values and worldviews. Renn and Levine (1991) argue that it is an impossible task for a risk communicator to affect this general normative debate in his favour because "there is no clear medium of communication available" for this level of debate (p. 210). Poortinga and Pidgeon (2005) even find that "communication efforts that are aimed at *directly* increasing trust may not be universally effective in solving risk controversies" (p. 207; cf. Fischhoff, 1995). At the same time, however, they argue, in line with our findings, that "trust wil be increased only through understanding and addressing the underlying concerns" (ibid). In this regard, "one must start with listening to the concerns of the public before giving them new information" (ibid.; cf. Bier, 2001). Through following the guidelines inherent in the *accountable risk communication* framework, businesses can prevent scenarios such as the one experienced by Monsanto from occurring. Therefore, we deem *accountable risk communication* to be a promising approach for business to adopt and for researchers to further investigate. Particularly the causal link between accountable risk communication and trust needs empirical validation. This would require a wide array of cases and statistical evaluation, which we are unable to provide at this point.

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Transatlantic Differences in GMO Regulation

A Case Study Approach

Lukas Bühl, Christian Malarciuc, Anna Völlmecke

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Introduction

"Sound science must trump passion"[1]
(D. R. Glickman, 1997)

When it comes to GMOs[2] the European Union (EU) and the United States (US) have chosen strictly opposing paths, although they were confronted with the same questions and information surrounding the GMO debate. With the statement above, Dan Glickman, the former United States Secretary of Agriculture, expressed his concern about the state of public opinion on biotechnology in Europe. It is a nice illustration of some of the differences and stereotypes surrounding the topic of genetically modified organisms (GMOs): whereas, for instance, the European regulatory system is generally characterised as politicised, decentralised and precautionary, the US system is often said to be the complete opposite, namely technocratic, centralised and sound science-based.

The strikingly different regulatory approaches towards GMOs have created an international debate regarding the production, cultivation and consumption of food made from or with GMOs. The different regulatory approaches employed by the EU and the US "created serious obstacles to the export of agricultural products from the United States, and in turn raised the prospect of a major international trade war over the approval and marketing of GM foods and crops" (Shaffer, 2004, p. 2). In 2003, the conflict culminated in a World Trade Organization (WTO) case[3] filed by the US, Canada and Argentina against the EU. Inter alia, the complainants challenged the unofficial de facto moratorium of the EU on the approval of biotech products and the national safeguard measures adopted by certain Member States (WTO, 2010). In 2006, the WTO ruled that the EU was indeed breaching its obligations under the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).

The regulatory differences in GMO regulation between the EU and the US have triggered a debate which has attracted the attention of scholars from various different disciplines and academic backgrounds. Jasanoff, for example, uses the concept of political

1 Urry, M. (1997, June 20). Genetic products row worsens. *Financial Times*, p. 4.

2 "Genetically modified organisms (GMOs) are organisms, such as plants and animals, whose genetic characteristics are being modified artificially in order to give them a new property. Food and feed which contain or consist of such GMOs, or are produced from GMOs, are called genetically modified (GM) food or feed" (European Commission, 2012).

3 Disputes DS291, DS292 and DS293.

culture to show that the different approaches taken by the EU and the US reflect "more or less self-conscious projects of nation-building" (Jasanoff, 2007, p.7). Vogel, by contrast, examines the regulatory differences from a political scientist´s perspective proposing three interrelated factors – the intensity of public pressure, the political preference of influential policy makers, and the criteria used for risk assessment – in order to account for the transatlantic regulatory divergence of GMOs (Vogel, 2012). Also jurists like Wiener and Alemanno have engaged in the topic focusing inter alia on the application of the precautionary principle in the EU and the US, or the role of the WTO (Wiener J.B., Rogers, M.B., Hammit, J.K., Sand, P.H., 2011; Alemanno, 2010).

However, while differences in GMO regulation between the EU and the US have already been widely examined on the regime level, particular case studies within this field have until now only been weakly explored. This is particularly surprising considering that both the EU and the US regime advance a case by case approach to GMOs – albeit in different ways. In light of this, the chapter has set out to accomplish two main objectives, namely a) to give a systematic review and synthesis of the scholarly insights on transatlantic differences in GMO regulation and b) to conduct two case studies in order to explore the question of whether and how case-studies could add to the existing scholarly body of knowledge.

While on the whole the results of our case studies seem to essentially prove Pollack's and Shaffer's claim that "once initial choices were made" the American and European systems have become "highly resistant to change" (2009, p. 34), they also lend to some speculations about potential trends on both sides of the Atlantic. Thus, we would like to argue that more case studies should be undertaken within this field and that the topic requires the continuing attention of scholars from various disciplines.

To give a short outline of the chapter, Section 1 will introduce and present our research approach, as well as give an explanation of the cases selected for this chapter. In Section 2, we will elucidate the respective GMO regulatory frameworks of the EU and the US and, subsequently, provide reasons for their divergence. We will do this by synthesising the broader literature on transatlantic differences in GMO regulation, resulting into an overview of the most important characteristics of the EU and the US system. Against this background, section 3 will describe and analyse the respective cases of GM Amflora (EU) and genetically engineered (GE) Alfalfa (US). Amflora was the first crop being authorised in the EU after the unofficial de facto moratorium, while Alfalfa was the first GMO authorisation that truly troubled the American judiciary. Finally, we will conclude the chapter with some final remarks and discuss how further research could add to the academic debate on transatlantic differences in GMO regulation.

1. Methodology

This section will describe in detail how research for this chapter has been conducted. It will outline the literature approach taken to the topic, as well as present three basic findings that could be drawn from the literature review. Section 1.2 will briefly explain why the respective cases of GE Alfalfa and GM Amflora were selected for this chapter.

Literature Approach and Review

Research for this chapter has been conducted in several steps. Initially, the chapter set out to systematically review the state of the art literature on transatlantic differences in GMO regulation. This process involved both the use of meta search engines,[4] as well as a thorough investigation of five selected journals.[5] Subsequently, a list of articles was established which revealed a pattern of the most prominent authors writing on transatlantic differences in GMO regulation. A smaller second investigation followed examining the aforementioned authors' further publications so as to determine their potential relevance for this study. Due to time constraints, however, not all references that this search yielded could be studied. Two criteria were therefore applied to select references: Overall relevance and academic discipline. While overall relevance was determined based on a quick scan of the article or book, the latter criterion – academic discipline – was applied with the goal in mind of having an adequate reflection of the vast range of disciplines that have so far engaged in transatlantic differences in GMO regulation. In total, nine books and 29 articles were reviewed providing the basis for this article.

Following the literature review, several conclusions could be drawn. First, *widespread attention has been devoted to the topic of transatlantic differences in GMO regulation*. In light of the literature studied for this chapter it can be safely concluded that the topic has been examined in great detail by a number of academic disciplines. Overall, it is therefore a well researched field. Second, *there are no opposing theories*. Within the scope of this chapter's literature review no analyses could be identified which accounted for the transatlantic regulatory differences of GMOs in fundamentally new and different ways than the rest of the studied literature. To be sure, however, not all authors emphasize the same set of explanatory factors, and even if they do they still often vary in degree

4 Wiley, Springer Link, UM's SFX.

5 The following five journals were searched for relevant contributions dating back as far as 2002: Science and Public Policy; Science, Technology & Human Values; European Journal of Risk Regulation; Social Studies of Science; and Journal of Risk Research.

and intensity. For example, some authors, such as Jasanoff (2005), focus particularly on *cultural* and *political* aspects, or more precisely on the concept of "*political culture*", while others stress above al *institutional settings* in order to explain transatlantic differences in GMO regulation. Yet others rely mainly on the concepts of "*precautionary science-based*" and "*sound science-based*" (Kleinman, Kinchy, Autry, 2009) to account for the transatlantic regulatory divergence, while others are critical of such stereotypes for they can be misleading and often conceal important interactions between the two systems (Murphy, Levidow, Carr, 2006).

As has been pointed out above, however, none of these analyses can be considered rival hypotheses. While slight deviations do exist, this does not mean that the analyses are incommensurable. There has only been one small "quarrel" between Jonathan Wiener and David Vogel focusing on the latter's proposed "flip-flop thesis". The thesis puts forth the idea that in some cases the US and the EU have switched "places with respect to the adoption of more stringent and comprehensive regulations" (Vogel, 2012, p.5). More specifically, it claims that the "US was more precautionary than Europe in the 1970s and early 1980s, but that Europe has become more precautionary since then" (Wiener, Hammit, Swedlow, Kall, Zhou, 2005, p.1). Wiener, however, chal enges this claim. Examining "the levels and trends in regulation of environmental, health, and safety risks since 1970", Wiener et al. come to the result that there has been "no significant difference in relative precaution over the period" (Wiener et al., 2005, p.2) Thus, "the[ir] results are [only] "weakly consistent with Vogel's flip-flop hypothesis" (p.15). In his latest book, however, Vogel responds to this criticism. Stating that he is only concerned with European and American "policy responses to . . . health, safety, and environmental risks *caused by business*" (2012, p.18, emphasis added). Vogel explains that Wiener's analysis "includes a number of policies that fal outside the scope of my [Vogel's] analysis" (p.18). Putting the dispute into the context of this chapter, we would like to quote Pollack and Shaffer (2009) and stress that we wil "resist characterizing either the US or the EU as the more risk-averse beyond the context of agricultural biotechnology" (p.43).

A third conclusion that can be drawn from the literature review is that *most of the analyses on transatlantic differences in GMO regulation are conducted on the regime level*. Although the topic is generally well researched, it is striking that very little attention has so far been devoted to particular case study – despite the fact that both the US and the EU regime advance a case by case approach to GMOs (albeit in different ways). As pointed out in the introduction, it has been mainly against this background that we decided to conduct two case studies, the results of which will be presented in section 3 of the chapter.

Case Search

Having completed the above described literature research, a "potential candidate list" was drafted via the databases from the International Service for the Acquisition of Agri-Biotech Applications (ISAAA),[6] the EU and the GMO-compass regarding GMO applications and authorizations. With a view to our research topic, the main search parameters applied were cultivation and authorisation. Ideally, we set out to analyse one single case which a) had been approved for cultivation on both sides of the Atlantic and b) appeared to diverge from the general picture of a lax US and a precautionary EU. This would have made the analysis more comparable, as well as interesting. However, no such case exists except MON 810 which does fulfil requirement a), not, however, requirement b) since it is fiercely debated in the EU, but has received almost no attention in the US. Since the field of biotechnology is furthermore a very fast developing field we decided that it would be more interesting to focus on recent GMO cases.[7] We therefore opted for a one-case-for-each-system path. Many interesting cases had to be turned down, because they missed authorization for cultivation in the EU and the US. Two cases did pass the test, however: BASF's Amflora and Monsanto's Round-Up Ready Alfalfa.

Both obtained cultivation authorizations, Amflora in the EU and Alfalfa in the US. Furthermore, at first sight both seem to trouble their respective system's characteristics, which wil be outlined in greater detail below. The Amflora potato is the first GMO receiving cultivation permission after the unofficial *de facto* moratorium on GMO approvals and happens to be an industrial needs only plant, which is also criticized for its use of antibiotics as markers. The GMO version of alfalfa was the first authorization to truly trouble the American regulator. Its authorization process was subject to various disputes troubling the American judiciary for more than five years. These two cases then, GM Amflora and GE Alfalfa, appeared to be the right candidates and seemed to make for an adequate contribution in terms of interesting case studies to be supplied.

6 The ISAAA is a global database providing insights into approvals of GMOs worldwide. Exploring the database we noticed that Japan appeared, as well as other Asian countries, very open to GMOs. It furthermore seems that market and global forces play a key role with biotechnology. Kleinman, Kinchy and Autry (2009) suggest that China, for instance, "is moving toward a more precautionary position on GM research and production in response to fears that GM products from China will be prohibited entry to European markets" (p.366).

7 MON 810 was approved in the EU in 1998 (GMO Compass, 2009), and in the US in 1995 (ISAAA, n.d.).

2. Explaining Transatlantic Regulatory Divergence

This section will give a detailed account of the existing legal frameworks of both the American and European system. After having explained and pointed out important differences, as well as similarities between the two legal systems, section 2.3 will go on to examine the various sources that have led to the transatlantic regulatory divergence of GMOs.

GMO Regulatory Framework European Union

Once spill-over mechanisms had driven the European legislator away from pure Internal Market affairs, the Community stepped forward to pass its first acts on environmental issues in a "series of directives" in the early 70's. The scope widened continuously and the precautionary principle had gradually become the basis for policy making in environmental affairs.

With regards to the regulation of GMOs the EU established a totally distinctive and new regulatory framework by adopting the 1990 Directive on the deliberate release of GMOs. Until 1990, every Member State was allowed to regulate GMOs on its own. The Commission, however, was soon concerned with the lack of harmonisation in this area and wanted to foster the development of the internal market by gaining regulatory authority.

Thus, the EU set up a new set of risk regulations governing the approval, cultivation and marketing of GMOs. However, the EU as such does not have the sole authority in regulating GMOs. The Member States still have the possibility to make use of a safeguard clause[8] that allows the temporal restriction of GMOs. The EU´s 1990 Directive paved the way for "a more precautionary socially oriented biotechnology policy than that obtaining on the other side of the Atlantic" (Jasanoff, 2005, p.92).

The specific legal framework regulating GM food and feed in the EU has been established in accordance with the precautionary principle. Filling this principle with life, the EU found that GMOs had to be "regulated by a *specific* (emphasis added) authorisation procedure" (Europa, 2011) Generally speaking, the authorisation of GMOs is based on the comitology procedure and essentially revolves around two legal documents: Directive 2001/18[9] covering the deliberate release of GMOs into the environment and the placing on the market of these, which repealed the first GMO Directive 90/220/EC and Regulation 1829/2003[10] concerning the placing on the market of genetically modified organisms and feed and food containing these. Certainly, each of these have undergone extensive

8 Art. 23 Directive 2001/18, [2001] O.J L 106/1.

9 Directive 2001/18, [2001] O.J L 106/1.

10 Regulation 1829/2003, [2003] O.J L 268/1.

amending which have been incorporated into this chapter, where necessary. Another document, Regulation 1830/2003 is concerned with the traceability and labelling of GMOs[11]. Finally, Regulation 178/2002[12] defines the role of the European Food Safety Authority (EFSA).

Sovereignty over the release of GMOs into the environment (cultivation) is initially left with the Member States, who are given 90 days to decide on an application, with an exceptional 30 days extension for a public consultation procedure. Yet, a notification and objection procedure has been put in place that centralises the authorisation process through the comitology procedure in Brussels, if objections are raised by other Member States or the Commission. This procedure also brings in EFSA for a central risk assessment. The same standard procedure has been put in place for the placing on the market of GMOs. In most cases objections were raised making the authorisation subject to the comitology procedure.

The application process starts with the applicants submitting his application to the national authority[13], which forwards it to EFSA. As of the day of a valid application EFSA is obliged to have finished its overall opinion within six months[14]. However, the time is stopped for the periods that EFSA requests additional information from the applicant[15]. EFSA submits its opinion to the Commission and to the Member States as well as to the public.

On the basis of the EFSA's opinion, the Commission draws up a draft decision in which it either approves or dismisses the operator's application. This draft decision is then forwarded to the Standing Committee on the Food Chain and Animal Health (SCoFCAH) within three months[16], where it is then subjected to a voting in this committee[17]. SCoFCAH is composed of representatives from the Member State.

If a qualified majority cannot be reached in SCoFCAH, the Council of Ministers will be called upon to take a decision within three months. Importantly, in case the Council of Ministers fails to reach a qualified majority against or for the draft, the Commission will continue and adopt the draft decision. This is the procedure under the old comitology

11 Regulation 1830/2003, [2003] O.J L 268/24.

12 Regulation 178/2002, [200] O.J L 31/1.

13 In accordance with Regulation 1829/2003, [2003] O.J L 268/1.

14 Arts. 6(1),18(1) Regulation 1829/2003, [2003] O.J L 268/15 "valid", and its implementing Regulation 641/2004, [2004]. O.J.L 102/14.

15 Arts. 6(4), 18(4) Regulation 1829/2003, [2003] O.J L 268/8.

16 Art. 7(2), Regulation 1829/2003, [2003] O.J L 268/1.

17 Ibid. 18
Council Decision 1999/468, [1999], O.J L 184/23.

procedure of Decision 1999/468[18]. A new comitology procedure has been put in place by Regulation 182/2011[18] in early 2011 which brought about some significant changes. However, since the case discussed in this chapter was still authorised under the old comitology procedure, the new procedure falls out of the scope of this chapter.

GMO Regulatory Framework United States

The Coordinated Framework for the Regulation of Biotechnology, handcrafted under the 1986 Reagan Administration, made the review of GM technologies subject to the existing network of institutional rules of the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the United States Department of Agriculture (USDA), hence a mosaic of federal laws. "[The] USDA and EPA are the agencies responsible for ensuring the safety of the agriculture and environment...[while the] FDA has primary responsibility for ensuring the safety of food and any food ingredient derived from genetic engineering (USDA, 2006, p.3). The USDA furthermore mainly operates through its Animal and Plant Health Inspection Service (APHIS) which "is responsible for protecting U.S. agriculture and the environment from pests, diseases, and weeds (USDA, 2006, p.5).

With no specific GMO regulatory framework put into place, the underlying premise of the Coordinated Framework was thus that "the process of biotechnology itself poses no unique risks and that products engineered by biotechnology should therefore be regulated under the same laws as conventionally produced products with similar compositions and intended uses" (Pew Initiative on Food and Biotechnology, 2004, p.1). More specifically, "Biotech products are regulated according to their intended use, with some products regulated under more than one agency" (USDA, 2006, p.7), as illustrated by the table below.

18 Regulation 182/2011, [2011], O.J L 55/13.

New trait/organism	Regulatory review by	Reviewed to ensure
Insect resistance in a food crop, e.g. Bt corn	APHIS	Safety for agriculture and the environment
	EPA	Safety for the environment and food and feed safety of PIPs
	FDA	Safety for food and feed use
Modified oil content in a food crop, e.g., oleic acid in soybean seed	APHIS	Safety for agriculture and the environment
	FDA	Safety for food and feed use
Herbicide tolerance in a food crop, e.g., glyphosate-tolerant corn	APHIS	Safety for agriculture and the environment
	EPA	Safety use of companion herbicide
	FDA	Safety for food and feed use
Herbicide tolerance in an ornamental crop, e.g., glyphosate tolerant marigold	APHIS	Safety for agriculture and the environment
	EPA	Safety use of companion herbicide
Modified flower color in an ornamental crop, e.g., blue carnation	APHIS	Safety for agriculture and the environment

Table 1 Regulatory Oversight of Biotechnology in the United States (USDA, 2006)

As mentioned above, APHIS regulates the introduction of GM plant varieties into the environment and "categorizes [them] ... *as potential plant pests"* (Pollack&Shaffer, 2009, p.47, emphasis original). With regard to the authorization of a crop like genetically engineered (GE) alfalfa one must therefore shift the focus to 7 U.S.C. (United States Code) §7711(a)[19], which confers the right "to prevent the introduction of *plant pests* into the United States or the dissemination of *plant pests* within the United States" to the Secretary of the USDA. A plant pest is any organism that can directly or indirectly injure plants, e.g. pathogens. According to the Plant Protection Act (PPA) "plant pests" are to be qualified as

19 U. S. C. §7711(a)

"regulated articles", unless stated different by APHIS[20]. Any person has the right to request APHIS to determine that the regulated article is not a plant pest, however, which would ultimately exempt the article from the regulations applicable to a plant pest. APHIS can comply with such a request for determination of non- regulated status that is absolving it from the applicability of the regulation for plant pests, either in whole or in part.

Significantly in this context, the National Environmental Policy Act of 1969 (NEPA) stipulates that federal agencies must prepare a detailed Environmental Impact Statement (EIS) to the fullest extent possible for "every … major Federal Actions significantly affecting the quality of the human environment"[21]. Yet, an EIS does not have to be carried out if APHIS, after having completed a shorter Environmental Assessment (EA), finds that the proposed action will not be significantly affecting the human environment.

European Union	United States
New and specific GMO regulation	Regulation under existing laws
Process based: GE products tested specifically for safety because of GE alteration	Product based: GE products tested against and like conventional products
Central GE testing authority: EFSA	No central GE testing authority: Mosaic of three agencies
Mandatory labelling (if GM product is above 0.9% content threshold)	No labelling obligation for GMO products. ("organic" defined as GMO free)
Politicized • Decisions taken by political bodies • Member states have safeguard clauses	Depoliticised (technocratic) • Decisions taken by independent regulatory agencies • States have no direct influence
Risk Assesment: Science Based	Risk Assesment: Science Based

Table 2: Schematic Overview of the Two Legal Regimes

Sources of Divergence

Any analysis seeking to explain the different approaches taken by the EU and US to the regulation of GMOs has to consider a multitude of factors. Scholars have attended to this issue in varying degrees. Based on the literature studied for this chapter, we found that Pollack & Shaffer (2009) take the most holistic approach to the topic. They identify

20 U.S.C sec 403 14 ju 411(a) ju 411(c)(1).

21 U.S.C §4332,2(c).

four factors: Interest group configurations, institutional arrangements, cultural values, and contingent events. However, while we agree with their overall conclusion – namely that the causes for the regulatory divergence have been a) multicausal and interactive, and that b) once initial decisions were made the respective systems have become highly resistant to change (Pollack & Shaffer, 2009) – we would like to take a slightly different approach to the topic.

First, we will provide some historical background. Second, based upon this, we will zoom in on the level of the public since differences in public perception and pressure played a key role in shaping the respective regulatory frameworks. When examining public pressure, we will include both contingent events, as well as cultural aspects, since we consider them to be inherently linked to one another. Third, we will briefly elaborate on institutional settings and the role they played, followed by some concluding remarks. By distinguishing between *historical background, public pressure*, and *institutional settings* we aim at incorporating the broader literature studied for this chapter. This way, we hope to do justice to the complexity of the topic, as well as the various academic disciplines that have devoted their time and effort to the issue.

Historical Background

During the late 1970s and early 1980s, the US and EU were confronted with the same questions, but "quickly took different paths" with regards to the "regulation of agricultural products produced by biotechnology" (Vogel, 2001, p.1). Different interests played a key role in this. In America, initial concerns about the safety of GMOs were soon "undermined by [a] growing awareness of biotechnology's commercial potential" (Vogel, 2001, p.1). Subsequently, the then ruling Reagan administration decided "to promote the development of a domestic agricultural biotechnology industry" (Vogel, 2012, p.73) – declaring GM foods to be substantially equivalent to their conventional grown counterparts, and thus safe (Vogel, 2001). This led to the Coordinated Framework for the Regulation of Biotechnology consisting of three main agencies (FDA, USDA, and EPA), as explained in section 2.2. Looking to promote biotechnology, GM crops were thus fast approved and subsequently used by a great numbers of farmers in America (Pollack & Shaffer, 2009). As a result, the US farm association became an important *supporter* of GM crops and foods which, in turn, eased the pressure on US regulators to adopt more stringent regulations for GMOs (Pollack & Shaffer, 2009). On the EU side, by contrast, almost the exact opposite happened. Opting for a process based approach, regulators recognised GM food to be inherently different, and thus potentially unsafe (Vogel, 2001). Consequently, biotech firms were not able to "get

early approval and early adoption of GM crops by farmers" (Pollack & Shaffer, 2009, p.70), so that pressure on regulatory officials for laxer GMO policies was accordingly weaker.

On both sides, however, public awareness and pressure played a key role. Strikingly, Europeans and Americans expressed very different attitude towards GMOs. While on the US side, low awareness of GMOs provided biotech firms with greater freedoms to shape biotech policy according to their own interests, Europe's public was generally much more sensitive, as wel as opposed to the introduction of GMOs (Carlarne, 2007). This, in turn, created a very different context for biotech firms to operate in. In the next section we will examine this phenomenon in greater detail. More specifically, we will explain why public attitudes, and hence public pressure, have been so different in the EU and US with regards to GMOs by linking it to contingent events, as well as cultural values.

Public Pressure

When trying to account for diverging American and European responses towards GMOs, many scholars have looked at the potential role played by contingent events, such as regulatory failures, in shaping people's risk perception of GMOs (Pollack & Shaffer, 2009; Vogel, 2012; Jasanoff, 2005). As Vogel (2012) explains, "the public typically does not view risks in isolation; rather, it links them to other risks about which it has heard" (p.292); thus, *"when* a particular risk emerges matters" (ibid.). As it pertains to the GMO debate, many scholars have pointed to the respective presence and absence of regulatory failures in the EU and US system in order to account for their diverging citizenry responses towards GMOs (Jasanoff 2005; Vogel 2012; Pollack and Shaffer 2005; Skogstad 2011). More specifically, whereas the EU experienced a major regulatory failure by the name of mad cow disease (hereafter BSE), the US did not (Vogel, 2012). Consequently, the BSE crisis is often seen as a (contingent) event which profoundly undermined the European public's trust into both policy-makers, as well as the regulatory system as such (Jasanoff 2005; Vogel 2012; Pollack and Shaffer 2005; Skogstad 2011). Although not causally linked to one another, the BSE crisis occurred at precisely the same time when biotech companies tried to introduce GMOs onto the European market prompting the public to connect the two events (Vogel 2012; Jasanoff, 2005).

However, while it has commonly been argued that increases in public demands for more risk- averse regulations are strongly intertwined with the public's *perception* of a particular risk (Vogel, 2012; Jasanoff, 2005), not any perceived risk must necessarily lead to heightened public pressure. Instead, as Vogel (2012) explains, "[I]ncreases in public demands to adopt more stringent risk regulations essentially stem from a gap between the public's perceptions of the risks they consider *both* (italics in original) credible and

unacceptable and the existing scope and stringency of government regulation" (p.37). Since notions such as credible and unacceptable are, however, culturally bound, it is important to pay attention to the broader cultural context within which contingent events take place.

As indicated by the German proverb, "andere Länder, andere Sitten . . . or other lands, other customs" (Jasanoff, 2007, p.3), culture matters. Particularly within the field of biotechnology, cultural predisposition should not be underestimated since, as Jasanoff notes, "by intervening in nature, biotechnology forcefully impinges on social meanings, identifies, and forms of life" (Jasanoff, 2005, p.14). On a rather basic level, for instance, some scholars have pointed out that Europeans show "strong preferences for natural food" (Vogel, 2012, p.34), whereas Americans are "more open to the use of new technologies in food production and preservation" (Pollack & Shaffer, 2009, p.73). Even more so than that, however, cultural values have played a key role in the general framing of biotechnology. As Pollack & Shaffer (2009) point out, in the US "agricultural biotech has been defined as an evolutionary development", whereas in Europe it "has been viewed as presenting a new form of technology . . ..raising broad social concerns" (p.69).

When analysing the potential role played by contingent events, such as regulatory failures, it is therefore important to be aware of the broader cultural context within which these event played out. With an eye to the notion of credible and unacceptable risks, it can be argued that the BSE crisis prompted Europeans to think of GMOs as constituting both credible and unacceptable risks. Combined with the loss of trust into their regulatory system, Europeans thus saw a discrepancy between the existing scope and stringency of government regulation and the perceived risks posed by GMOs. On the US side, by contrast, no similar policy or regulatory failure took place which, in turn, reassured the public of the proper functioning of their regulatory system (Vogel, 2012). The "relatively passive acceptance of GM food in the United States" is therefore usually not ascribed to a "lack of concern about the risks", but rather seen as a reflection of the high level of trust Americans have "in the[ir] food safety regime" (Sheingate, 2006, p.127).

Thus, to sum up, contingent events, above all the respective presence and absence of regulatory failures in the EU and the US, have played a key role in shaping divergent risk perceptions of GMOs. Taking place within a distinct cultural context, they affected the level of public trust into both regulatory officials, as well as the system as such. As a result, the intensity of public pressure for more risk-averse regulations diverged, shaping in turn the final policy decisions made on both sides.

Institutional settings

Institutional differences are another important factor that helps explain why the US and EU have taken different approaches to the regulations of GMOs. Vogel, for instance, argues that the "regulatory governance structure of the EU has provided a wide range of opportunities for those opposed to GMOs to participate in the policy process and has made European regulatory policies more responsive to their preferences" (2012, p.91). Europe's overal precautionary attitude towards GMOs is thus ascribed to its more decentralised and politicised decision-making process at the EU level – above all the heightened role it gives to politicians and the ability of member states to invoke safeguard clauses with regards to GMOs (Pollack & Shaffer, 2009; Vogel, 2012). By contrast, the American system is said to be much more "centralised" and depoliticised "resulting in a more science-based approach that is less responsive to populist sentiment mobilized by anti-GMO activists" (Pollack & Shaffer, 2009, p.72). Unlike the EU where decisions are taken by "political bodies such as the Council of Ministers, the Commission, and European Parliament", the US relies on "specialized regulatory agenc[ies] such as the FDA" (p.10).

However, while governance structures may be an important factor, they cannot by themselves account for the transatlantic regulatory divergence of GMOs. If the EU's more precautionary approach to GMOs were the result of its unique institutional character, one would have trouble explaining all the other policy fields in which the US takes a more precautionary stance than the EU[22]. Institutional differences only played a role insofar as that they provided each relevant actor with a distinct set of opportunities and constraints (Pollack & Shaffer, 2009). Since, however, from the outset American and European attitudes towards GMOs diverged, it is questionable if different governance structures alone could have made the US more, or the EU less precautionary towards GMOs. As Vogel puts it, "institutions . . . may represent a necessary condition . . . [but] are not a sufficient condition" (2012, p.291). Overal , therefore, it must be concluded that "institutional differences between the US and the EU did not, in themselves, determine the different approaches to biotechnology taken by the two sides" (Pollack & Shaffer, 2009, p.73).

22 For an empirical investigation of the relative level of precaution between the US and EU see Wiener J.B., Rogers, M.B., Hammit, J.K., Sand, P.H. (2011).

Summary

Before moving on to the next section, two important conclusions have to be drawn. One, no single factor can account for the regulatory polarisation of the European and US system with regards to GMOs. Put differently, the two approaches taken by the EU and US "were not determined in any straightforward way" (p.11). Rather, as has been explained above, the two systems have emerged from the complex interaction of cultural, institutional, and contingent factors. This, in turn, created a context which provided each actor with distinct opportunities, as well as constraints to pursue their interests. Second, although not pre-determined, "once the respective US and EU regulatory frameworks were adopted, they proved remarkably resilient in their essential characteristics" (p.34). Below we present a short overview of what we consider to be the most important differences between the European and US system. While we are aware that important interactions have also taken place *between* the two systems[23], we nevertheless think that their distinct approaches lend to a broad juxtaposition, as undertaken below. Against this theoretical backdrop, we will now analyse the respective cases of GE Alfalfa and GM Amflora.

	US	EU
View on Biotechnology	Substantially Equivalent (Assumption: safe)	Inherently Different (Assumption: unsafe)
Approach to Biotechnology	Product based	Process based
Risk Management Approach	Sound science-based	Precautionary Principle
Desicion Making Style	Administrative, Technocratic Centralised (Politically)	Politicized Decentralised (Politically)
Public Trust Into Regulatory System	High	Low
Public Awareness	Low	High

Table 3 Schematic Overview of System Characteristics

23 See Murphy, J. & Levidow, L. (2006).

3. Case Studies

This section presents the respective cases of GM Amflora and GE Alfalfa. Each case will be first described and then analysed. At the end of each analysis each case will be furthermore compared to their respective system characteristics, as outlined above.

European Union: The Case of GM Amflora

Amflora[24] is a potato variety developed by Germany, Ludwigshafen based BASF Plant Science GmbH. The potato was created to supply the starch-dependent industry, such as glue and paper producers (BASF, n.d.) with an improved source of starch. The initial application was filed with the Swedish authorities in 1996 (BASF, 2010), but was then affected by the *de facto* moratorium on GMO approvals in the EU between 1998 and 2004. Once the moratorium had come to an end, in January 2003, BASF lodged their application for cultivation. Yet, "since it cannot be excluded that the GMO potato [Amflora] and derived products may be used as or may be present in food, [t]he GMO panel was . . . requested to carry out a comprehensive scientific risk assessment of the GM potato [Amflora] for all uses" (EFSA, 2006a, p.4), i.e. BASF submitted an application for food and feed use in 2005 as wel .[25]

The European Commission, after having received objections from ten Member States[26], requested an opinion from EFSA[27]. The general criticism being, that Amflora contains an antibiotic resistance marker gene. This gene "could be transferred from the potato cel s to bacteria dangerous to humans. Such a migration would reduce the effectiveness of these antibiotics in humans" (Corporate Europe Observatory, 2011). According to article 4(2) of the Deliberate Release Directive, GMOs containing these specific genes have to be taken into particular consideration when carrying out an environmental risk assessment.

However, on November 10, 2006 EFSA released its overall opinion on the application concluding "that the potato EH92-527-1 [Amflora] is unlikely to have an adverse effect on human and animal health or the environment in the context of its intended uses" (EFSA, 2006a, p.2). Both applications have then been dealt with under the rules of the comitology procedure. The Commission forwarded its draft proposal for the authorisation

24 Event-name:EH92-527. Name for labeling according to arts 13(1),15(2) Regulation 1829/2003, [2003] O.J L 268/1 and art 4(6) Regulation 1830/2003, [2003], O.J L 268/24: "amylopectin starch potato".

25 In accordance with Regulation 1829/2003, [2003] O.J L 268/1.

26 Austria, Belgium, Cyprus, Denmark, France, Germany, Italy, Lithuania, Spain and the UK.

27 In accordance with Directive 2001/18, [2001] O.J L 106/1.

of Amflora to the Regulatory Committee but neither the committee was able to reach a qualified majority either against or for the authorisation of Amflora nor was the Council of Agricultural Ministers. Consequently, since in neither instance a decision could be reached, the task was passed to the Commission. Instead of directly taking a decision, in May 2008, the Commission requested a consolidated opinion on the use of antibiotic resistance marker genes in genetically modified plants. Commission President Barroso announced that the Commission will adopt the pending decision "if and when" EFSA confirms the safety of Amflora (BASF, 2010).

In May 2008, BASF Plant Service requested access to all the documents that had been in the possession of the Commission concerning the authorisation of Amflora. The documents did not expose any new scientific evidence concerning the safety of Amflora. In July 2008, BASF filed an action with the European Court of First Instance against the Commission´s failure to act (ibid.). On June 11, 2009 EFSA published its third positive opinion so that finally, the Commission gave its approval for the authorizations[28] for food and feed uses[29] [30] and for cultivation[31] in March 2010.

Hungary is currently summoning the Commission before the European Court of Justice to have the decisions approving Amflora for food and feed and for cultivation squashed[31]. Luxembourg and Austria have joined the suit with Hungary in the meantime (Greenpeace, 2010).

Case Analysis

As has been pointed out earlier, the EU regulatory system of GMOs is often characterised as politicised, decentralised, process oriented, as well as rather precautionary in its approach towards GMO regulation (Pollack & Shaffer, 2009). The overall acceptance amongst Europeans is more reluctant compared to its American counterpart and the public is generally more distrustful of its regulator due to certain food scandals such as BSE (Jasanoff 2005; Vogel 2012; Pollack & Shaffer 2005; Skogstad 2011). However, looking at the (GM) potato Amflora one might question whether these stereotypes hold true.

28 Decision 2010/136/EU [2010], O.J L 53/15 (for food and feed) and Decision 2010/135/EU, [2010], O.J L 53/11 (for cultivation).

29 Articles 7(3) and 19(3) Regulation 1829/2003, [2003] O.J L 268/1.

30 Article 18(1) Directive 2001/18, [2001] O.J L 106/1.

31 Case T-240/10: Action brought on 27 May 2010 – Republic of Hungary v European Commission, O.J. C 209, 31.7.2010, p. 46–47.

As already outlined above, in March 2010, the Commission authorised Amflora for cultivation and for food and feed uses. It is only the second crop granted the approval for cultivation in the EU[32]. At first sight it therefore seems as if Amflora would break the general picture of an EU that is precautionary and reluctant in granting approval for cultivation. However, in the following we will see that this hypothesis cannot necessarily be substantiated. In fact, the approval process of Amflora was marked by strong political disagreements resulting in an approval process that took more than thirteen years.

In the case at hand the most important actors have been the institutions of the EU, including the Commission, the Parliament and the Council of Ministers who are the key actors in the decision making process. Furthermore, the Member States as such played a significant role in shaping the approval process, as well as other actors such as NGOs and of course the company BASF itself.

The role of the Commission was rather atypical in the process of authorisation. In all of the GMO cases before, "EFSA's opinions were considered as an authoritative source of expertise . . . [but in the case of Amflora] the Commission initially decided to give more weight to the objections raised by the Member States" (Weimer, 2010, p.649). During the safety assessment stage of the authorisation procedure, EFSA submitted two positive assessments stating that "there is no evidence to indicate that the placing on the market of potato EH92-527-1 [Amflora], for use in cultivation and starch production, is likely to cause adverse effects on human and animal health or the environment" (EFSA, 2006a, p.17) as wel as that "potato EH92-527-1 [Amflora] and derived products are no more likely to cause adverse effects on human and animal health or the environment than conventional potatoes" (EFSA, 2006b, p.17). Consequently, both applications submitted by BASF were granted a positive risk assessment by EFSA. Nevertheless, neither the Committee nor the Council were able to reach a decision on the draft decision by the Commission to approve Amflora for authorisation of cultivation and for food and feed use.

According to the approval procedure outlined above, it would have been the Commission´s task to adopt the proposal. However, due to political disagreements this did not happen. It becomes obvious that the EU regulatory regime of GMOs is indeed politicized as has been suggested by the literature discussed above. There are many channels for influential policy makers to engage in the decision making process. One of the crucial policy makers has been the responsible European Commissioner for the Environment Stavros Dimas. The "somewhat critical attitude of Stavros Dimas towards gene technology"

32 The first crop being approved for cultivation was the Bt maize MON 810 by Monsanto in 1998.

(Biotechnology, 2010), led to an ongoing postponement of the authorisation process. One could even state that "Commissioner Dimas failed to adhere to the approval procedure" (BASF, 2010), since it would have been the Commission´s task to adopt the proposal.

Not only the rather critical attitude towards GMOs by the responsible Commissioner itself but also the voting behaviour by the Committee, and the Council of Agricultural Ministers led to a deadlock since they were neither able to reach a qualified majority in favour of the Commission´s draft proposal nor against it. Because of this split within the EU countries on whether to allow the authorisation or not, it was in the end the Commission who "ended up legislating on the issue" (Dudek, 2011). In contrast to Commissioner Dimas, "it seemed that President Barroso and Commissioner Dalli [European Commissioner for Health and Consumer Policy] were leaning favourably toward the acceptance of GMOs" (p. 15).

Furthermore, the approval of Amflora was accompanied by fierce lobbying on the part of BASF itself. The company sent an open letter to the Commission, or more precisely to Commissioner Dimas, requesting and pressuring for the approval of Amflora (BASF, 2008). Additionally, BASF even took legal action against the Commission at the Court of First Instance for its failure to act under Article 18(1) of the Deliberate Release Directive (Transparenz Gentechnik, 2008). In May 2008, the Commission decided to request EFSA to prepare a new consolidated scientific opinion on the use of antibiotic resistance marker genes. At the same time, under lobbying pressure by BASF, EU Commission President Barroso finally declared that Amflora would be approved as soon as EFSA could confirm the safety of the antibiotic resistance marker gene (BASF, 2010).

The political struggles outlined above, confirm the assumption that the EU is politicised especially compared to the US. The observation, that public pressure is playing an important role in shaping the debate surrounding GMOs is visible as well. Luxembourg, Austria and Hungary try to fight the Commission´s decision to authorise Amflora, containing the antibiotic-resistance gene, in front of the Court of Justice of the European Union (Greenpeace, 2010). Especially in Germany there had been fierce protests against the authorisation of Amflora. For instance, meadows where field trials were conducted were destroyed (Norddeutscher Rundfunk, 2011).

Another factor contributing to the long authorisation procedure have been external circumstances. As already outlined above, the authorisation procedure took thirteen years. In August 1996 the first application was filed but ended up being exactly in the period of the *de facto* moratorium. The moratorium can be framed as a "contingent event" (Pollack & Shaffer, 2009). Due to the moratorium, the authorisation procedure was on ice. Furthermore, Amflora was the first plant to be approved for cultivation under the new regulatory regime. According to one employee of BASF, the regulatory changes taking

place between 2002 and 2004 played a crucial factor in the course of the authorisation (Interview Britta Stellbrink, 2012). Summing up, although at first sight the authorisation of Amflora seems atypical as such, the political struggles and the long authorisation procedure show that the politicised and decentralised structure of the EU is still in place. The authorisation process was not smooth and straight forward, but was full of hurdles and discontent by many actors leading to conflicts of interest. In the aftermath this becomes even more visible. Recently, BASF announced to move its BASF Plant Science headquarters to America due to a *lack of acceptance*.

"'We are convinced that plant biotechnology is a key technology for the 21st century. However, there is still a lack of acceptance for this technology in many parts of Europe – from the majority of consumers, farmers and politicians. Therefore, it does not make business sense to continue investing in products exclusively for cultivation in this market,' said Dr. Stefan Marcinowski, member of the Board of Executive Directors of BASF, responsible for plant biotechnology." (BASF, 2012)

In an interview with an employee of BASF, it was stated that there is no cultivation of Amflora anymore and that the company immediately stopped all the research projects for plants that are purely for the European market (Interview Britta Stellbrink, 2012). Furthermore, as a result of the authorisation of Amflora, the Commission created a proposal that would give the Member States the possibility to make independent decisions on the cultivation of GMOs on their territory (Europa, 2010). This proposal was initiated as a result of the political flurry surrounding the authorisation of Amflora and a call by thirteen Member States.[33] Thus, although public pressure cannot explain why the Commission approved Amflora, it may be an explanation for the Commission´s proposal to give the Member States the possibility to take the final decision. However, public pressure has definitely been one of the reasons for BASF to move its headquarters to America and stop the cultivation of Amflora.

33 AT, BG, IE, EL, CY, LV, LT, HU, LU, MT, NL, PL, SI.

	EU	Amflora
Risk Management Approach	Precautionary Principle	Ambiguous: • Long approval *process*, but eventually approved • Commission proposal signals even greater precautionary measures
Decision Making Style	Politicised Decentralised (Politically)	Confirmed: • Great involvement of politicians and political bodies in approval process Confirmed: • Decision taken by political bodies such as the Commission
Public Trust Into Regulatory System	Low	Unable to make empirically valid assertion – further research needed
Public awareness	High	Confirmed – Potentially Increasing • BASF moves its headquarters away from Europe to the U.S.

Table 4 Overview of GM Amflora compared to important EU system characteristics

United States: The Case of GE Alfalfa

Alfalfa is America's fourth largest crop being grown on over 20 mil ion acres (Center for Food Safety, 2011a). "Known as the queen of forages, alfalfa hay is the primary pasture feed for dairy cows, conventional and organic alike" (Center for Food Safety, 2011a). With a view to assist farmers foraging on alfalfa, the American based biotechnology company Monsanto developed a genetically modified variant of alfalfa in cooperation with Forage Genetics. The Roundup Ready Alfalfa provides in-plant tolerance to the glyphosate based herbicide roundup which was developed and commercialised by Monsanto in the late 1970s (Monsanto, 2012). In theory all weeds are eradicated by the application of Roundup, except the tolerant plant itself, e.g. Roundup-Ready Alfalfa. Consequently, on April 16, 2004, Monsanto and Forage Genetics submitted a request for determination of nonregulated

status under 7 CFR part 340.6 a)[34] for their Roundup Ready Alfalfa lines J101 and J163 with the United States Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (hereafter APHIS) (APHIS, 2010).

After having assessed the plant risks posed by the alfalfa lines, APHIS prepared an Environmental Assessment (EA) in which it identified and evaluated "any environmental impacts on the human environment that could result from the approval of the [application]" (APHIS, 2010, p.i). On June 27, 2005, APHIS decided that the two alfalfa lines did "not present a plant pest risk . . . [and were therefore] no longer regulated articles under regulations at 7 CFR Part 340[35]" (APHIS, 2005, p.4). Following APHIS's decision, many GMO opponents started to voice their displeasure. They expressed concerns about the potential contamination of organic and conventional alfalfa, as well as the worsening "of the ongoing epidemic of glyphosateresistant weeds" (Center for Food Safety, 2011b). They also pointed out that 93 % of the alfalfa planted in the United States is grown without the use of any herbicides at all, making Roundup Ready alfalfa superfluous to begin with (Center for Food Safety, 2011a). Subsequently, in 2005 the "Center for Food Safety (CFS) along with farmers and other environmental and consumer organizations filed a lawsuit against the United States Department of Agriculture (USDA)" (Center for Food Safety, 2011c).

On February 13, 2007 Judge Breyer of the Federal District Court, Northern District of California ruled that the USDA's "approval of Monsanto's genetically engineered (GE) Roundup Ready alfalfa was il egal" (Center for Food Safety, 2007). The judge furthermore decided to ban "any further planting of GE alfalfa" until APHIS had carried out an Environmental Impact Statement (EIS) for the two alfalfa lines (Center for Food Safety, 2007). It marked the first time that the USDA was required to undertake such an analysis for any GE crop (Center for Food Safety, 2011a). In November, 2009, APHIS released its Draft Environmental Impact Statement (DEIS) in which it proposed to "grant nonregulated status" to the two alfalfa lines "based on the agency's analysis . . . [that they] are unlikely to pose plant pest risks" (APHIS, 2009, p.xi i). In response to this, "more than 244,000 people submitted comments to the USDA critiquing the substance and conclusions of its Draft EIS on GE Alfalfa" (Center for Food Safety, 2011a) Moreover, 56 members of Senate and House decided to "sent a letter to Secretary Vilsack asking USDA to retain the regulated status of genetically engineered (GE) alfalfa" (Center for Food Safety, 2010).

34 http://www.law.cornell.edu/cfr/text/7/340 last checked May 26, 2012.

35 Ibid.

After holding meetings for feedback on the draft, APHIS eventually released its Final Environmental Impact Statement (FEIS) on December 16, 2010. In it, APHIS proposed three alternatives in regards to the two alfalfa lines: (1) not granting deregulation, (2) granting full deregulation, or (3) granting deregulation in part by means of certain restrictions that would promote coexistence with conventional and organic alfalfa lines (APHIS, 2010).

On February 2, 2011, APHIS announced that it opted for alternative (2) stating that the two alfalfa lines "are unlikely to pose a plant pest risk and are [therefore] no longer to be considered regulated articles und APHIS's biotechnology regulation at 7 CDR part 340[36]" (APHIS, 2011a). On March 18, 2011, the Center for Food Safety filed again a lawsuit against the USDA arguing that the deregulation of Roundup Ready alfalfa was unlawful (Center for Food Safety, 2011a). The case is still ongoing.

Case Analysis

As has been pointed out in section 2.3, the US regulatory system of GMOs is generally characterized as administrative (technocratic), politically centralized, as wel as "sound science-based" in its risk management approach. Regulatory agencies are said to enjoy a high level of public trust contributing to the overall acceptance of GMOs amongst Americans. In the following, we will discuss if the above described case of GE Alfalfa largely confirms these system characteristics, or rather disproves them.

As the description above indicates, GE alfalfa has been a truly controversial case troubling the American judiciary for many years. The Environmental Impact Statement (EIS), which APHIS was ordered to carry out for the first time, as well as the temporary ban on the planting of GE alfalfa in 2007, had been celebrated by GMO opponents as potentially "precedent-setting" (Center for food safety, 2007). However, what the subsequent, and still ongoing, pursuit of legal actions above all achieved was to open up an otherwise centralized, and "politically insulated" (Pollack & Shaffer, 2009, p.72), GMO approval system. Amplified by an attentive and alert media, GE alfalfa caused more public and political scrutiny than any previously approved GMO – creating in turn more opportunities for opponents to voice their opinion, as well as participate in the decision making process. The stakeholder meeting convened by USDA Secretary Thomas Vilsack on December 20, 2010 is a case in point. Following the release of APHIS's Final Environmental Impact Statement, he invited a diverse group of people "representing different interests and viewpoints in the GE, organic, and non-GE agriculture sectors, as wel as consumer

36 Ibid.

interests" (APHIS Documents, n.d.) in order to find an adequate solution to the problems posed by GE alfalfa.

Also of importance in this context is that GE alfalfa received political attention. More specifically, "Sen. Patrick Leahy (D-Vt.) and Rep. Peter DeFazio (D-OR), joined by 49 other representatives and five other senators sent a letter . . . to U.S. Department of Agriculture Secretary Tom Vilsack asking USDA to retain the regulated status of genetically engineered (GE) alfalfa" (Center for Food Safety, 2010). The letter was, moreover, endorsed by 50 businesses and came as a response to the earlier released Draft Environmental Impact Statement (DEIS) in which APHIS concluded that "genetically-engineered alfalfa lines are unlikely to pose plant pest risks . . . [and] will not result in significant impacts to the human environment" (APHIS, 2009, p.xi i). The fact that a number of politicians felt the urge to weigh in on the alfalfa case is noteworthy from the perspective that, unlike in Europe, key risk management decisions are not taken by political bodies, but by specialized agencies, such as the FDA, EPA, or in this case the USDA's APHIS (Pollack & Shaffer, 2009).

Furthermore, as has been pointed out earlier, the US system is often described as a sound science based system, in contrast to the EU who is said to be much more reliant on the precautionary- principle. Indeed, the USDA itself states in its Strategic Plan that it "uses a science-based regulatory system . . . which allows for the safe development and use of agricultural goods derived from new technologies" (2010). Interestingly, however, the term "sound science-based" was also used by the *opponents* of genetically engineered alfalfa, who claimed that the USDA was in fact "ignor[ing] sound science" (Institute for Responsible Technology, n.d.a).

APHIS' Final Environmental Impact Statement (FEIS), as wel as some of its other documents, furthermore provide some insights into his risk assessment behaviour. More specifically, it might be speculated as to whether APHIS engaged in what many scholars have called boundary work. As Asselt & Vos (2008) explain:

> "Boundary work involves drawing and maintaining contrasts through selective attributions, which effectively demarcate in order to construct 'self-evident justification' and 'superiority in designated terrains' (Gieryn 1999). It has been convincingly demonstrated that boundary work is not just a matter of formal responsibilities, but that it is an ongoing negotiation process on roles and tasks and how these are portrayed to others" (p.288)

For instance, while in his FEIS, APHIS does discuss the potential far-reaching implications

of GE alfalfa, such as gene flow, contamination of organic alfalfa, as well as weed-resistance, in its final conclusion for deregulation it nevertheless feels the need to draw specific attention to the agency's "mission" which is "to protect American agriculture from the introduction and dissemination of *plant pests* (emphasis added)"; thus, it continues, "APHIS conducted a plant-pest risk assessment . . . which indicated that both GT alfalfa lines J101 and J163 are no more likely to pose a plant pest risk than other alfalfa varieties" (2010, p.10). In his official Question and Answer Fact Sheet, APHIS explicitly states that it made the decision to fully deregulate GE alfalfa "because RR [Roundup Ready] alfalfa did not present a greater plant pest risk than other conventional alfalfa varieties" (2011). Even more revealing, asked why it (APHIS) did not opt for alternative (3) – granting "commercialization of GT [glyphosate tolerant] alfalfa . . . [but] using a combination of restrictions . . . to promote coexistence" (APHIS, 2010, p.11) – APHIS replied:

> "APHIS decided not to choose alternative 3 because RR alfalfa did not exhibit a greater plant pest risk in the geographically restricted areas described in alternative 3. Therefore *it would not be consistent with APHIS' regulatory authorities*" (APHIS, 2011b, emphasis added)

That APHIS may have engaged in some form of boundary work might also be reflected by Sen. Patrick Leahy's comment, made in the abovementioned letter, that the USDA, and hence APHIS, had "taken an impermissibly *narrow view of its regulatory authority*" (Center for Food Safety, 2010, emphasis added). As mentioned above, the letter came as a response to APHIS's Draft EIS in which it already proposed to grant nonregulated status to the two alfalfa lines (APHIS, 2009).

It can furthermore be argued that APHIS's conclusions display what Asselt & Vos (2008) have identified as "uncertainty intolerant assessment behaviour" (p.286) – meaning that "uncertainties are not acknowledged, deemed irrelevant, or are simply evaded instead of genuinely and systematically investigated" (p.284). As has been shown above, APHIS usually phrases its final decisions using terms such as "no more likely", "unlikely", or "no greater risk than". Sometimes the agency even goes as far as to construct *complete* certainty. For instance, in his Final EIS APHIS asserts that "GT alfalfa *has no adverse effects* (emphasis added) on human health and worker safety" (2010, p.vi i). It lies beyond the scope of this chapter to give a full and detailed analysis of APHIS risk assessment behaviour. However, we think that it is an issue deserving further attention – particularly within the broader context of risk assessment and the characterisation of the US system as "sound science-based".

Moving to another aspect, however, the alfalfa controversy may also lend to some speculations about the broader acceptance and awareness of GMOs in America. While the literature often speaks of a passive acceptance of GMOs amongst Americans, it is noteworthy that "more than 244,000 people submitted comments to the USDA critiquing the substance and conclusions of its Draft EIS on GE Alfalfa" (Center for Food Safety, 2011a). Important in this context is also that, since GE alfalfa is "the fourth most widely grown crop in the US, with approximately 23 mil ion acres in production" (Pollack & Shaffer, 2009, p.270), the GE alfalfa case is not only a dispute between organic farmers and biotech companies, but also includes conventional farmers, as well as concerned consumers who fear that they will soon not be able to buy organic anymore (Center for Food Safety, 2011a).

Furthermore, it can be speculated as to whether the controversy round GE alfalfa benefitted from some contingent events. For instance, the fast growing 'Just Label It' campaign in America, as wel as the attempted marketing of a genetically modified salmon currently under review by the FDA (Institute for Responsible Technology, n.d.b) may have made the GE alfalfa case more salient in the media. As Harmon and Pollack from the New York Times write, "the current push for labeling in this country stems, in part, from a broadening of the genetically modified menu to include herbicide-resistant alfalfa and the possible approval this year of a fast-growing salmon" (2012). As it pertains to the broader significance of the GE alfalfa case, it might be therefore argued that it has either triggered or been part of a broader movement in America. The relative success of the 'Just Label It' campaign, which claims to have already sent over a million comments to the FDA demanding mandatory labelling (Center for Food Safety, 2012), as well as the several polls and surveys which show that more than 90% of Americans are in favour of labelling requirements (Center for Food Safety, n.d.), could be read as an indication of this.

Nevertheless, it is important to note that, despite public outcry, the USDA did deregulate GE alfalfa in the end. Even more so, the USDA recently announced that it wil try "to cut by half the time needed to approve biotech crops from the current average of three years" since "approvals that took six months in the 1990s have [nowadays] lengthened because of increased public interest, more legal chal enges and the advent of national organic food standards" (Kaskey, 2012).

To sum up: viewed against the theoretical backdrop of the US system characteristics the controversy round GE alfalfa involved many atypical developments. The pursuit of legal actions and court injunctions against the USDA's deregulation decision, as wel as increased media attention, opened up an otherwise centralized and technocratic GMO regulatory process, exposing it to more public, as well as political scrutiny. Stakeholders

were more involved than usually and the characterisation of the US system as being "sound sciencebased" has been shown to be not without its shortcomings, deserving further academic attention. Public awareness of GMOs might be furthermore increasing, while public trust into the regulatory system might be on the decline. Altogether, however, it is doubtful as to whether GE alfalfa can be seen as a "picture breaking" case, let alone be a "game- changer" that wil fundamentally transform current GMO approval practices in the US. To be sure, the comparatively high (and continuing) media coverage of the case, as well as its ongoing litigation process, do lend to some speculations about its broader significance for the American GMO debate. Overall, however, our research seems to show that, while slight changes in external circumstances appear to take place, the unconditional deregulation of GE alfalfa largely points to the essential *continuity of the US system*, thus proving Shaffer and Pollack's point that "once initial choices were made", the US system, just like that of the EU, has become "highly resistant to change" (2009, p. 34).

	US	GE Alfalfa
Risk management Approach	Sound Science Based	Questionable – further research needed
Decision Making Style	Administrative, Technocratic Centralised (Politically)	More open and participatory: • Stakeholder meeting • Use of legal action • Political attention • Media salience Confirmed: • Final decision solely taken by USDA
Public Trust Into Regulatory System	High	Potentially on decline (speculative)
Public awareness	Low	Potentially Increasing (speculative)

Table 5 Overview of GE alfalfa compared to important US system characteristics

Conclusion and Discussion

This chapter started out by explaining the GMO regulatory regimes of the EU and the US. Having systematically reviewed and synthesized the scholarly insights on transatlantic differences in GMO regulation, we arrived at an overview of what we considered to be

the most fundamental aspects separating the US and the EU with regards to GMOs. Against this backdrop two GMO cases were analysed: GE Alfalfa, on the US side, and GM Amflora, on the EU side. Ideally, we set out to analyse *one single case* which a) had been approved for cultivation on both sides of the Atlantic and b) appeared to diverge from the general picture of a lax US, and a precautionary EU. This would have made the analysis more comparable, as well as interesting. However, no such case exists[37] except MON 810 which does fulfil requirement a), not, however, requirement b), as discussed in section 1.2. The decision to conduct two case studies was based on the fact that most analyses on US and EU differences around GMO regulation have been conducted on the regime level, not, however, on the level of particular cases. Hence, we attempted to explore the question of whether and how casestudies could add to the existing scholarly body of knowledge.

Overall, our results suggest that case study can indeed add to the discussion on transatlantic differences in GMO regulation, and should therefore receive more scholarly attention. To be sure, from a broad perspective both GE alfalfa, as wel as GM Amflora, are reflective of their respective system's characteristics, and seem to essentially prove Shaffer & Pollack's claim that "once initial choices were made" the American and European systems have become "highly resistant to change" (2009, p. 34). GE alfalfa may have been the first authorization to truly trouble the American judiciary – being met with public and political opposition alike – but final authority lay once again with the USDA alone which decided to deregulate it; by contrast, GM Amflora not only went through a difficult approval *process*, but continued to spark opposition even *after* its approval – prompting BASF to eventually move their headquarters away from Europe to the US. From this perspective, therefore, both cases appear consistent with the idea that the US system might be overall less precautionary than the EU. Nevertheless, we would also like to argue that the two case studies lend to some speculations about potential trends and changes on both sides of the Atlantic.

On the US side, for instance, it could be argued that the relative success of the 'Just Label It' campaign, triggered in part by the controversy around GE alfalfa, points to a certain level of unease among at least some Americans. The use of legal action against the USDA, as well as the continuing public outcry caused by the alfalfa decision, might be read as modest signs that a growing number of Americans starts to question the legitimacy of the US regulatory

37 The fact that we could not find a case that fulfilled both of our requirements can already be seen as a finding in itself. It shows that there are still stark differences between the two systems in terms of how they regulate GMOs. Nevertheless, it remains to be seen if either side might change their position in the future leading to more convergence between the two systems.

system. The often asserted passive acceptance among Americans in regards to GMOs might therefore be challenged. Unfortunately, however, we did not come across any reputable pollster that could empirically confirm this hypothesis, so that case study might be the only way to investigate this matter in more detail. During our research we furthermore came across a number of other interesting cases[38] which are currently discussed in the US and which could potentially generate even more public opposition to GMOs.

On the EU side, by contrast, it can be argued that although GM Amflora has been authorised by the Commission, when zooming into the case it becomes visible that the EU as such is not becoming laxer but is rather on a path towards becoming more precautionary. From the outside, the authorisation might point towards less precaution. When looking at the political dynamics within, however, and the aftermath of the approval – such as the Commission´s 2010 proposal for Member States to decide on the cultivation of GMOs as well as the removal of the BASF headquarters from Europe – the precautionary nature of the EU regulatory framework is clearly visible. There are more GMOs[39] in the pipeline for authorisation in the EU, but even if these GMOs are going to be authorised, it would be a fallacy to draw the conclusion that the EU is changing towards a laxer regulatory system. In this context further case studies could help to analyse the dynamics surrounding these cases instead of drawing conclusions by solely taking into account the outcome.

Finally, we would also like to point out several limitations that have been encountered in the course of this paper. One fundamental limitation has to do with the topic itself: exploring transatlantic differences in GMO regulation is a highly complex undertaking. It has therefore been beyond the scope of this paper to attend to every aspect with the same due diligence. We are furthermore aware of methodological weaknesses inherent to the comparison between the two cases and their system characteristics. The latter is certainly no ideal comparator. Instead, it would have been better to select two cases from each system and analyse them against one another. This way, more empirically sound relativity could have been established. However, due to time constraints and the fact that

38 One such case would be Aqua Bounty's GM salmon which could make for an interesting analysis. It is the first animal to be put up for approval for human consumption. Currently under review by the FDA, it might be interesting to see if this case will generate more widespread opposition to GMOs. As it involves a living animal, it could give rise to a new kind of conversation about GMOs, one that focuses more on ethical aspects, rather than health, environmental, or economical aspects. Roundup ready sugar beet might be another interesting case to investigate, as it also involved a legal dispute.

39 "BASF Plant Science will continue the regulatory approval processes for the products already started" which include inter alia two starch potatoes called Amadea and Modena as well as one potato for consumption which is called Fortuna (BASF, 2012).

we could not draw upon already existing case studies within this field, we were only able to select one case per system. We therefore think that a bigger pool of case studies could help arrive at more empirically sound conclusions about potential trends and changes in the two systems.

Furthermore, any follow up case study would probably do best by focusing on only one particular aspect that is said to separate the two systems. For instance, we think that issues pertaining to risk assessment behaviours deserve to be given more attention and could present a promising and new research field. Excel ent work has already been done on EFSA's risk assessment behaviour,[40] but we are not aware of any studies that have analysed American and European risk assessment behaviours from a cross-comparison perspective, for instance by comparing EFSA's risk assessment with that of APHIS's.

In the end, exploring transatlantic differences in GMO regulation is a complex endeavour. While, however, a lot of great work has already been done on the regime level, case studies remain an underrepresented field. This is regrettable since subtle changes or trends taking place on both side of the Atlantic might go unnoticed when focusing exclusively on the regime-level. We therefore encourage anyone with an interest in the topic to conduct more case studies. This way more empirically sound conclusions could be drawn about the two systems, which could potentially give rise to completely new insights on transatlantic differences in GMO regulation.

40 Pioneering work has been done by Asselt, M.B.A. & Vos, E. (2008), see references.

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Citizen Participation in the Regulation of GMOs:

The Case of Austria

Marisol Bock, Rebekka Goeke, Tobias Kalt & Caspar Kolster

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1. Introduction

Genetically modified organisms (GMOs) pose one of the most salient and openly discussed challenges to risk regulators on the EU and national level. They can be classified as a so-cal ed "uncertain risk"[1]. The public perception of green biotechnology as an uncertain risk resonates in many citizens' disapproval of the authorization procedures for GMO food, feed and seed on the EU and national level. While legal facts were created by the legislators, beginning in the year 1990 with the ratification of Directive 1990/220/EC and ensuing national legislation, the popular concern with GMOs took longer to form. More recently, this has led to ambiguity with both the public and the legislators as to who is competent to authorize GMOs and who is to enforce compliance with the regulation. This situation can be regarded as a symptom of what Giddens (1991) has coined the "post-trust society", in which the citizen's confidence in the regulator's competence has eroded. Several other scholars have investigated the pitfalls of risk regulation and forwarded possible remedies, most notably the increased inclusion of citizens in the regulatory process (Löfstedt, 2005; Renn, Klinke, van Asselt, 2011; Stirling, 2008). While there is abundant theoretical literature on the topic, little research has been conducted on the actual phenomenon of citizen participation[2] in the regulation of GMOs in the EU.

The aim of this paper is to scrutinize the participation processes through which citizens influence legislative practice, as well as to research the translation of public input into policy outcomes. Both aspects are relevant to evaluate citizen participation as such. When researching the translation into policy outcomes, i.e. the effects of participation, we must note the pitfall of confounding variables which lies in assuming a causal relationship between two correlating factors. Therefore any deductions made from correlating participation practices and policy shifts need to be assessed carefully. Through our work we intend to advance the scholarly debate on citizen participation by including non- institutionalized participation into the analysis, an aspect which has largely been neglected to this point. Our motivation is to draw conclusions from our social-scientific analysis as to the greater awareness and improvement of citizen participation mechanisms,

1 'Uncertain risk' are characterized as "possible, new imaginable hazards, with which society has no or limited experience and whose risk potential is consequently unknown" (van Asselt & Vos, 2008, p. 281).

2 Although we refrain from using "public participation" as a term, and replace it with "citizen participation", the word "public" is used as a synonym for "citizens". With the term citizen participation we solely refer to individual or interest group initiated participation, excluding potential other stakeholders, such as companies or scientific communities.

and to provide a new angle on the legal deadlock of regulation. To this end, we study the case of GMO regulation in Austria, a European country in which there is strong opposition to GM food, feed and seed[3] as well as a correlation of citizen attitudes and national policy outcomes. On that account, the broad question we aim at investigating is the following:

How are the citizens involved in national GMO regulation in the European Union?

Our paper is divided into five parts: Firstly, we introduce citizen participation and its democratic value. Secondly in the methodological section, we present our research strategies to approach citizen participation by creating a checklist of commonly used methods and establishing evaluation criteria for them. Thirdly, we outline the relevant legal background, and participatory events in Austria. Fourthly, we analyze and discuss our research findings derived from desktop research and semi-structured interviews and lastly, we draw conclusions as to the reality of citizen participation and give according recommendations.

2. Citizen Participation

Anthony Giddens (1991) has coined the term 'post-trust society' to describe current modern society, which has grown so complex that no single person can fully comprehend the resulting profusion of different processes and phenomena. Consequently, citizens are compelled in some areas to trust experts and political decision-makers who claim to make the right decisions on their behalf. Giddens defines trust as the "confidence in the reliability of a person or system regarding a given set of outcomes or events where that confidence expresses a faith ... in the correctness of abstract principles ([i.e.] technical knowledge)" (Giddens, 1991, p. 34). However, in post-trust societies, trust is gradually disappearing. In the field of risk regulation this is especially evident. Hence, with regard to political decisions on the acceptance of uncertain risks, one function of the inclusion of citizens is to rehabilitate public trust in risk governance (Van Asselt & Vos, 2008).

In dealing with uncertain risks, the orthodox approach to risk governance does not prove suitable anymore. Traditionally, risk governance has been a technocratic process based on a Newtonian approach to science that searches for universal laws without

3 According to the Special Eurobarometer on Biotechnology 60% of the Austrian population believe that GMOs in foodstuffs "are not good for them or their family" and 68% believe that it is "not safe for future generations" (Eurobarometer, 2010).

exceptions (Mitchell, 2009). Since the end of the twentieth century, the proliferation of uncertain risks, e.g. in the form of genetic modifications, and the inadequacy of technocratic decision-makers to deal with those, as exemplified by the 1996 BSE crisis (Wynne, 2001; Ansell&Vogel, 2005), prompted the search for alternative ideas on how to govern uncertain risks. Many scholars (Wynne, 2001; Renn&van Asselt, 2011; Löfstedt, 2005; Stirling 2008) have made the case for the inclusion of the public into risk governance. These scholars put forth strong reasons of why citizen participation should become institutionalized as an integral part of risk governance. First, there is the already mentioned need to rehabilitate trust in political decisions on risks. In this sense, public participation is often regarded as a value in itself. As such, it fosters legitimacy as well as responsiveness of public institutions and is therefore a prerequisite for sound governance. Furthermore, more effective risk communication that is staged as a dialogue between the regulator and the public can increase public trust in political decisions and the effectiveness of law. Second, participation increases the equity and fairness of the political process since the public now has an influence through their norms and values on which risks should be tolerated. Third, as scientific knowledge is never purely objective but is always shaped by certain commitments and assumptions, participation offers a possibility to allow for alternative public perspectives to be considered as a valid source of knowledge (Löfstedt, 2005, p. 18). The previous four arguments for inclusion of citizens are also supported by Jürgen Habermas (1996), who has developed thoughts on both the legal and political dimension of sustainable and inclusive law-making. He describes how the mere existence of means for citizen participation is not sufficient to provide legitimation for a legal act, as it does not guarantee that each participant of the process regards the legal act itself and its coming into existence as normatively justifiable. As a result, in Habermas' view, a legal act can only be regarded as thoroughly legitimated if both the process of formulating the law includes those later concerned and the act itself facilitates further participation.

Other scholars in the field show that a differentiated view on citizen participation is crucial. Drawing on the ideas of Niklas Luhmann (1969) who describes how procedures serve to legitimize and stabilize the prevailing political order by allowing conflicts to be carried into the system, and subsequently resolving conflict potential through procedures embedded in the law, Frank Rodrigues (2012) has pointed out that citizen participation should not be uncritically hailed as the perfect democratic solution to the problems of dealing with uncertain risks. Instead, he shows how participation can become scientificated, i.e. it must justify itself with reference to a meta-norm based on rationalist science, and thus excludes other 'antirationalist' perspectives, such as ethical norms and values. Thus, there is the risk that participation that ought to empower the

public actually disempowers it, if citizen participation ends up being caught in the net of governmentality[4]. In this way, conflict potential is absorbed and co-opted whilst citizen participation is instrumentalized in order for the state to establish certain norms and legitimize policy outcomes.

In sum, many risk governance scholars advocate the inclusion of citizens in risk governance through institutionalized forms of participation, whilst also emphasizing the perils of hailing participation uncritically or taking for granted that the mere provision of participatory possibilities is sufficient to legitimize legal acts. This approach to studying participation is in line with L. Graham Smith's definition of participation as encompassing "a group of procedures designed to consult, involve, and inform the public to al ow those affected by a decision to have an input into that decision" (in Rowe & Frewer, 2000, p.6). As Depoe, Delicath & Elsenbeer (2004) have pointed out, the focus in studies of citizen participation in environmental decision-making has been traditionally on "citizen involvement in institutionalized settings with specific mechanisms and forums for engagement with government officials and other stakeholders" (p. 255). However, this approach leads to the exclusion of other forms of citizen participation that are not organized along a top-down trajectory by the state, examples of such practices being public protests and other types of citizens' actions (cf. Renn, Webler & Wiedemann, 1995; Van Asselt & Rijkens-Klomp, 2002). In this paper, we broaden the definition of participation that focuses on institutionalized participation to also include participation that occurs outside of the institutionalized framework, i.e. non-institutionalized participation. This categorization of citizen participation is in line with that of James Petersen (1984), who distinguishes between government- mandated participation and grassroots participation. In our analysis we make use of i*nstitutionalized citizen participation (ICP), representing government-mandated citizen participation and non- institutionalized citizen participation (NICP)* as referring to any other type of citizen participation, including grassroots participation (1984, p. 4-7). ICP is organized and regulated from the top down, whereas NICP originates from the bottom up, commonly initiated by citizens or other actors with a particular interest in the topic. These types of citizen participation in the field of agro-biotechnology take place outside of the institutionalized scope, yet they may also have an impact on policies. Hence, they are of relevance when examining citizen participation in risk governance.

4 Governmentality is a term coined by Michel Foucault. He described it as the exercise of power through "institutions, procedures, analyses and reflections, the calculations and tactics" which has as its target the creation of a well-ordered and stable society (Foucault, 1991: 102). This goal is tried to be achieved by employing a certain kind of knowledge though the apparatuses of the state.

3. Methodology

The following chapter introduces the methodological background applied in the analytical part of the paper. We first define methods of participation along the lines of our institutionalized and non- institutionalized citizen participation distinction. Second, we establish criteria of evaluation that are useful to assess the respective methods and third, we derive some hypotheses from our theoretical discussion that help to guide the analytical research on the case.

3.1 Participation Methods

The notions of institutionalized citizen participation (ICP) and non-institutionalized citizen participation (NICP) categorize participation according to the organizer or sponsor. Based on a literature review we are able to distinguish specific methods of participation in both categories (for a detailed overview of all methods, see appendix A).These potential methods of participation then, can be compared with the actual events from the case study of Austria. First, in the category of ICP (see appendix A, table 1) we are able to identify methods of open participation for all interested citizens. These include public hearings, public opinion surveys or referenda. Additionally, we can distinguish methods in which citizens receive an exclusive invitation to participate, such as negotiated rule-making, consensus conferences, citizen's jury or panel, citizen/public advisory committee, focus groups and parliamentary committees. Furthermore, the degree of active participation needs to be considered for every event in particular, i.e. whether participants are allowed to engage in a discussion, ask questions to experts or regulators or are supposed to remain passive listeners to other participants (cf. Rowe & Frewer, 2000, Table 1, pp.8-9; Van Asselt and Rijkens-Klomp, 2002). Second, NICP (see appendix A, table 2) can be further subdivided into activities carried out foremost by individual actors interested in the issue, such as citizens' initiatives, letter writing or consumer boycotts, and activities facilitated by third actors such as NGOs, i.e. demonstrations, petitions or property damage. However, the distinction adopted from Kaase (1999) is somewhat blurry due to the potential use of all methods by interests groups such as NGOs.

3.2 Participation Evaluation Criteria

In order to assess the democratic value of ICP and NICP, this section sets out evaluation criteria for the legitimacy and effectiveness of participation methods. The distinction between these qualities is derived from the political sociologist Seymour Lipset's theory on democracy in his work *Political Man* (1969). He identifies effectiveness and

legitimacy as two correlated, necessary conditions of a stable democracy. Effectiveness is an instrumental quality and refers to actual performance, i.e. the extent to which the basic functions of a political system, as most of the population see them, are delivered. In contrast, legitimacy is evaluative. Groups deem a political system to be legitimate or illegitimate according to how the values promoted through the system fit their own values. In our work, rather than applying legitimacy and effectiveness to an entire political system as Lipset does, we employ them to test the political device of citizen participation. Hereby, effectiveness remains instrumental in character, addressing the policy outcome whereas legitimacy is evaluative, targeting the process of participation.

In order to assess aspects that are unique to ICP, we subdivide the criterion legitimacy into *independence* and *representativeness*. This approach is derived from Gene Rowe and Lynne Frewer's (2000) account of legitimizing factors of democracy and provides us with an adequate means of evaluation. With regard to independence, institutionalized participation should aim to create a sort of ideal speech situation, i.e. a situation that is free from constraints of agenda and protocol. With regard to representativeness, those who take part in ICP should be representative of the wider public. To this end, members of every social group should be included in the process. The relative distribution of standpoints should be taken into account as small samples with representatives of every viewpoint may lead to the diminution of the views that the majority holds. Furthermore, institutionalized participation needs to allow for several different forms of participation, because few participation opportunities with small samples can lead to deviations from the actual common views held by the people (Rahl, 1996). With regard to NICP, the foci of analysis to rate legitimacy are more difficult to distinguish. We thus scrutinize the mobilizing actors from a wider angle of legitimacy alone. For this purpose, we regard legitimacy based on the number of people who were mobilized, as well as the diversity of their backgrounds. We further check. the mobilizing actors' role in activating and forming public opinion, according to their degree of independence from particularistic interests, i.e. from third-party interests, as well as personal interests, as opposed to common public interests.

A second criterion to evaluate participation as a democratic process is effectiveness. Effectiveness describes how much the public influences political decisions through its participation. In order to measure this criterion, we will examine the responsiveness of political decision-makers to change policies in reaction to citizen participation. If changes in policies follow participation events, we can assume high effectiveness of participation. However, we will not be able to demonstrate clear causal links between participation and policy outcomes, as changes may also result from other circumstances, such as economic pressures or political strategies.

3.3 Hypotheses

In order to evaluate citizen participation according to the legitimacy and effectiveness criteria, we first define hypotheses, second, conduct our case study, and third, review the hypotheses in order to verify or reject them in the discussion part of the paper. Derived from the state-of-the-art literature on risk governance (cf. Renn et al., 2011; Stirling 2008) and as outlined in the previous section on citizen participation, we assume to find out that ICP has more of a democratic value than NICP. Thus, our two hypotheses are that *ICP is more legitimate than NICP* and that *ICP is more effective than NICP*. The following analysis part, structured into a case description, case discussion and subsequent interpretation of findings scrutinizes these hypotheses.

4. Analysis

4.1 Case Description

4.1.1 Case Choice: Austria

As mentioned in the introduction, the majority of Austrians are pessimistic towards GMOs5. Among many other acts of defiance, in 1997, approximately a fifth of the population expressed its discontent with the leniency of authorization procedures by signing a popular petition to ban all GM food, feed and seed in Austria (Hoppichler, 2010). In the aftermath, the Austrian government firstly imposed a ban on the import of GMOs which was maintained until 20036. Secondly, it supported the group of member states in the EU Council inhibiting the Commission action to enforce compliance with directives and regulations on GMOs. Thirdly, the Austrian government has submitted a proposal to amend existing EU legislation to widen the argumentative basis, on which a safeguard measure against GMO imports can be invoked, to also include ethical and socio-economic concerns[7] next to health and environmental safety reasons[11]. Lastly, on the regional level, the Austrian constituencies have been ratifying their own precautionary

5 The rejection was very general. Volker Helldorff as a proponent of popular opinion states "If it is Mon810 or Mon811 or Mon812 or Mon728, that's all the same rubbish!" (Interview, 2012, Appendix E.2 p. 73)

6 The EU maintained a moratorium on the authorization of more GMOs between 1999 and 2003, after Austria, along with 5 other member states had imposed import bans (Euractiv, 2012).

7 The GTG phrases these concerns as fear of „social incompatibility of products" (Article 63). In practice, this cannot be applied due to the legal contraints emanating from EU law. [11] Council Proposal 2010/0208.

legislation (Lebensministerium, 2012). There seems to be a lot of political effort towards the realization of goals which are congruent with citizens' interests. Hence, there is a correlation between the citizens' demands and policy outcomes. The strong participatory efforts and the corresponding political change in course on GMOs are ideal conditions to investigate the practicalities of citizen participation.

4.1.2 Case Description: participation in GMO regulation in Austria

The following section provides a chronological overview of citizen participation around the regulation of GMOs in Austria. It can be subdivided into three phases, starting with *pre-mobilization* (phase I) before 1996, when the public was relatively unaware of issues related to biotechnology and citizen participation was almost non-existent (Torgersen, 2002, p. 176). In 1996, a period of *mobilization* (phase II) began when the salience of GMOs rose, after the tabloid press had commenced to emphasize the dangers of GMproducts. Large parts of the public were outraged and citizen opposition towards GMOs culminated in a popular petition in April 1997. Up to 2001, we can observe increased public awareness and participation (Seifert, 2003, p.107). From 2001 on and until the present day, the public engagement has *slowed down* (phase III) significantly. For each of these phases, we outline (a) legal acts, (b) institutionalized participation opportunities, (c) non-institutionalized participation measures, and (d) the respective bases of argumentation for both forms of participation.

Phase I: Pre-Mobilization

a. Legal acts

The debate on biotechnology and other peripheral debates slowly began in the 1980s. At the time, it was unclear what type of regulation was needed, as products had not entered the market yet (Torgersen, 2004, p. 6). The Austrian public was mostly indifferent and scarcely informed on the matter and remained so until 1995, when Austria joined the EU and therefore had to comply with the EU's acquis and legislative framework (ibid., p. 176). The first relevant piece of legislation was passed on the European level, with Directive 1990/220/EC. This act established standards for authorization and the deliberate release of GMOs. In accordance with its statutes, a competent member state authority could object to the placing on the national market of a GMO on health and environmental safety grounds, using the safeguard clause enshrined in Article 16 of the directive. The Austrian legislator had already transposed this directive into its national law on genetic engineering (Gentechnikgesetz, short GTG) in 1994, before joining the EU.

b. ICP opportunities

Prior to the formulation of the GTG, the first-ever committee of inquiry (Enquête-Kommission) in the parliamentary history of Austria was formed in order to pre-empt the outbreak of a potential public controversy. Yet it excluded citizens and only allowed for the participation of scientific experts and parliamentary representatives (Seifert, 2003, p. 107). Moreover, under the statutes of the GTG, the public had to be notified in a public hearing prior to the release of a GMO onto the market. Furthermore, any citizen could send in a letter of objection.

c. NICP

There was merely one NGO *(Gen-ethisches Netzwerk,* GeN), consisting only of one member, involved in the public debate on GMOs. Its activities did not gain much public attention since the public was largely uninformed in matters of biotechnology (Seifert, 2003, p. 107; Torgersen, 2002, p. 176).

d. Basis of argumentation

ICP opportunities, as set out in the GTG, foresaw the same basis for objections enshrined in the EC Directive, i.e. environmental or public health risks[8]. Popular concern was underdeveloped at the time Seifert, 2012). Nevertheless, the only salient non-institutionalized actor, GeN, placed a strong emphasis on ethical concerns (hence the name Gen-ethisches Netzwerk).

Phase II: Mobilization

a. Legal acts

The GTG was revised in 1998 to include more detailed provisions on the procedure of public hearings, liability and information of the public[9]. One important change was the introduction of the right of local communities, farmers and neighbours of farmers who are affected by the release, to appeal to ministerial decisions about authorizations of GMOs[10](Umweltbundesamt, 2000, p. 18). Furthermore, the EU replaced Directive 1990/220/EC with the newly drafted Directive 2001/18/EC. This act aimed to centralize the authorization procedure for GMOs in the EU. It also entailed Regulation 178/2002

8 GTG Art.60, 1994.

9 BGBl. I Nr. 73/1998.

10 BGBl. 2, Nr.61/1997, Art. 29, 44 GTG.

establishing the European Food Safety Authority (EFSA) and labelling standards for products containing GMOs. From 1999 to 2004, a de facto moratorium on further authorizations of GMOs was in place on EU level.

b. ICP opportunities

The 1998 revisions to the GTG relate back to the work of a special parliamentary committee on the popular petition (Sonderausschuß zur Behandlung des Gentechnik-Volksbegehrens) that was set up to deal with the popular petition. It consisted of parliamentary representatives but also included the initiators of the petition (two representatives of Greenpeace and Global2000) and Prof. Dr. Peter Weish, a biologist and engaged citizen (OTS, 1997). The committee work was supposed to consider the popular demands and integrate them into a legal proposal addressed to the parliament. Yet, in 1998, both the Austrian National Law, petition representatives and the Greens quit the committee due to their dissatisfaction with the proposal (Petrovic, 1998).

Eventually, the GTG revisions of 1998 established new criteria for who was to be considered a stakeholder in the authorization procedure and improved the procedural framework for authorization concerns and subsequent public hearings. For instance, the geographic sphere of stakeholders and spread of information was increased to neighbouring communities and the accessibility of documents improved. Otherwise, there were no changes concerning the participatory framework[11].

c. NICP

Mobilization of citizens was triggered by a media campaign of the tabloid paper, Kronen Zeitung[12] against the cultivation of genetically modified plants after the unauthorized release of a GM potato in 1996 (Grabner, 2000, p. 132). This campaign spawned increased public tentativeness with regard to GMOrelated topics. Greenpeace and Global2000, a subsidiary of Friends of the Earth, were two of the most active NGOs and during this time strongly involved in creating awareness of the issue. Among other forms of protest, they initiated the occupation of ministerial offices in 1996 to convince the Minister of Public Health, Christa Krammer, to issue an import ban on GM seeds (Greenpeace, 2007). Public discontent with GMO regulation gained momentum after these events and a conglomerate of NGOs, an organic farmers' association, retailers and a Christian consortium managed to

11 Austrian National Law, BGBl. I Nr. 98/2001.

12 The Kronen Zeitung is the most widely read national newspaper in global comparison (circulation in relation to number of inhabitants); it reaches around 50% of the Austrian population (Der Standard, 2010).

collect the signatures of 1.2 million Austrians in a popular petition to ban GMOs (Seifert, 2003). The petition demanded an import ban on GM-food, a ban on the cultivation of GMOs in Austria and on the patenting of any form of life[13]. Further, less salient activities of the opponents of GMOs included a tractor marathon by organic farmers and the public dumping of corn to raise awareness of the issue (Seifert, 2003). Moreover, efforts to reverse the unauthorized cultivation of GM-maize in 2001 were made by Greenpeace which organized the government-mandated destruction of fields on which GM seed had been sown (Greenpeace, 2007). Hitherto, this was the second incident in which a GMO producer had violated the law by cultivating GM-crops without prior governmental authorization, which caused great public outrage (Seifert, 2003, p. 107, Grabner, 2000, p. 133).

d. Basis of argumentation

The argumentative basis on which objections to the authorization of GMOs could be built did not change during this period of time. Discourses in ICP evolved along the lines of environmental and health concerns whereas the popular demands promoted an anti-GMO stance in every respect; environmental, healthrelated, ethical as well as socio-economic.

Phase III: Slowdown

a. Legal acts

During this phase, the Austrian parliament passed further revisions of the GTG, none of which entailed changes to the legal standing or participatory possibilities of citizens[14]. Other legal actors now gained influence. The regions (*Bundesländer*) released a set of precautionary laws on GMOs (*Gentechnikvorsorgegesetze*) in a coordinated effort to make GM cultivation virtually impossible (Lebensministerium, 2012; BMG, 2012). On the other end of the legislative spectrum, the EU's Lisbon Treaty was ratified and introduced the European Citizens' Initiative (ECI) opening up the possibility for the opponents of GMOs all over Europe to directly appeal to the EU on the issue[15]. Furthermore, the Austrian

13 Attachment 715 the stenographic protocols of the plenary session of the national assembly XX: GP, concerning the popular petition to the parliament.

14 Austrian national law,BGBl. I Nr. 94/2002, BGBl. I Nr. 94/2002, BGBl. I Nr. 73/2004, BGBl. I Nr. 126/2004, BGBl. I Nr. 127/2005, BGBl. I Nr. 13/2006.

15 The ECI, established by Regulation 211/2011 must be supported by at least 1 M. Citizens from at least 7 member states.Other, though previously existing "soft measures to appeal to the European Union are listed in Article 228 TFEU, which establishes the Ombudsman as a spokesperson for popular concerns, Article 236 TFEU, which allows for an individual appeal to the European Court of Justice (ECJ) to evaluate an existing legal act, Article 227 TFEU, which establishes the possibility to direct a petition to the EU Parliament as a concerned individua l or group. 20 Council Proposal 2010/0208.

government issued a proposal of its own to amend the existing EU legislation to include ethical and socioeconomic grounds for a ban of GM-products[20].

b. ICP opportunities

In 2006, a joint conference of the Commission and Austria was held to discuss the coexistence of GM- and non-GM seeds in Vienna. The list of guests was extensive and stakeholders, among others farmers and NGO representatives were invited but attendance was only granted upon invitation (Commission [DG Agriculture], 2006).

c. NICP

The non-institutionalized response to this summit was the "Vienna Declaration" by the NGO network GENET, which promotes the regulatory sovereignty of GMO-free regions. The main aim of the Vienna Declaration was to refute the idea of coexistence and implement changes to EU legislation (GMO- freeregions, 2006). In 2008, as one of the few acts of public resistance, environmental activists attached a banner to the Ministry of Health on the occasion of the newly appointed minister of health entering into office (Greenpeace, 2012a). Moreover, the treaty changes on the EU level led to a petition initiated by Greenpeace Europe directed at the European Commission. The NGO managed to collect over one million signatures from citizen of all member states of the EU in less than a year (Greenpeace, 2009). The petition was rejected by the Commission since the Regulation 211/2011 determining the details of an ECI had not yet been passed[16].

d. Basis of argumentation

There are a number of legal bases and distinct proposals during this phase, which makes it difficult to trace one legitimate and coherent basis of argumentation. Austria upholds their national law, which is in line with current EU legislation and at the same time proposes changes to EU law[22] The Commission has not yet decided whether it will initiate the changes to the safeguard clause that Austria has demanded. Moreover, recalcitrant legal acts of the *Bundesländer* further complicate the question of who is the legitimate regulator and what is to be the standard of food safety. The correct argumentation for or against a ban can thus hardly be determined.

16 Before, petitions had been directed at the EU institutions and national governments, e.g. "save our seeds" and "stop the crop" (safeourseeds, 2002; GMO free regions, 2012). The success of these petitions however was limited, since they were soft tools overruled by hard EU law (saveourseed campaign, 2002; Global2000, 2012).[22] Council Proposal 2010/0208.

4.2 Case Discussion

Derived from our three-phased case description and the interviews with activists and experts in the field, in the next section we identify the most relevant events related to the policy making of agro- biotechnology regulation in Austria. Based on the methodological distinction of institutionalized versus noninstitutionalized citizen participation, the relevant participatory events are evaluated from the viewpoint of legitimacy and effectiveness in order to assess the level of citizen influence on the policy process and correlated outcomes. We begin with the institutionalized mechanisms and complement these with noninstitutionalized practices to be able to draw a holistic picture of citizen participation efforts in Austria and evaluate the democratic value of participation in risk governance.

4.2.1 Discussion ICP

From our case description, few relevant forms and procedures of institutionalized citizen participation could be determined. Therefore, we focus our discussion first on participation in the form of public hearings prior to GMO authorizations and second, on the special parliamentary committee that was set up to deal with the popular petition after 1996. The parliamentary committee of inquiry set up for drafting the 1994 GTG could have been an arena for citizen involvement, however the fact that only experts and parliamentarians took part disqualifies it from being considered as ICP in our analysis. The same applies to the coexistence conference 2006, organized jointly by the Austrian government and the European Commission which did not allow for public involvement, yet triggered a lot of NICP alongside the event.

Legitimacy Public hearings

Public hearings refer to the officially mandated hearings, according to the GTG, following a release request by a GMO producer. As outlined in the descriptive section, some changes of the law were made over time, improving the formal hearing procedure. When assessing legitimacy in ICP we can distinguish between the level of representativeness and independence as outlined previously in the methodology section. First, the degree of representativeness can be evaluated as rather high. After the publication of a specific GMO release request, every citizen is allowed to submit a written complaint and subsequently will be invited to the hearing. However, this procedure does not produce any binding outcomes but solely allows participants to speak up and voice their opinions vis-a-vis the regulator. Second, with regard to independence, whereas the hearing procedure is supposed to facilitate an open space for discussion and exchanging views, i.e. provide

an ideal-speech situation, participants claim that this has not been the case in some early meetings (Seifert, 2003). Prior to 1998, participants felt that their concerns were not taken into account. This was for instance, reported in 1996, at a hearing concerning the field trial release of a GM-potato. The majority of the participants left the hearing due to the perceived unwillingness of the ministry to engage in a dialogue about the benefits and dangers of the release. One of the participants, a researcher in microbiology, described the process as "a catastrophe because it was organized insanely badly [...], by the representative of the ministry who organized it. He just sat there and the people talked but he didn't permit any answers"[17] (Seifert, 2003, p. 116). Yet, after 1998 legal amendments to the GTG, the right to appeal to ministerial decisions was extended. However, due to the moratorium on GMO authorizations and the following bans on the deliberate release by the Austrian government, there were hardly any more public hearings. In sum, we can say that representativeness was rather high as opposed to the level of independence, with regard to public hearings organized by the government.

Special parliamentary committee on the popular petition

Regarding the special parliamentary committee's work from a *representativeness* perspective, it can be evaluated as flawed. Whereas the citizen representatives[18] had expected to be strongly involved in writing a proposal acknowledging their demands, and finding acceptable compromises, they eventually left the committee as a sign of protest and dissatisfaction (Petrovic, 1998). One of the parliamentary members of the Greens described the committee's work as a "mockery of the initiators of the popular petition"[19]. This shows a severe lack of representativeness in the process, as the citizen representatives were not given a strong voice against the large opposition by the ruling parties. Furthermore, concerning the *independence* of the actors, the chair of the committee and member of the conservative ruling party (ÖVP) Dr. Nikolaus Zacherl, was accused of working at the same time as a lobbyist for the biotech- industry (Petrovic, 1998). Due to the low involvement of the citizen representatives and vested interests that may have been at stake, the independence of the process must be evaluated as rather low. Representativeness, on the other hand is to some extent given, due to the participation of

17 Translation from:„Das war ja eine Katastrophe. Weil das irrsinnig schlecht organisiert war. Also die Vertreter des Ministeriums, die das geführt haben. ... Der hat sich da einfach hingesetzt und die Leute haben geredet und er hat nicht darauf antworten lassen.

18 Represantatives of the NGOs and Prof. Dr. Peter Weish.

19 Translation from: einer Verhöhnung der Initiator/inn/en des Volksbegehrens (Petrovic, 1999).

citizen representatives. Yet, their number was less than proportional to other members of the committee, as only the initiators of the petition were invited and the committee was closed to other interested citizens.

Effectiveness

With regard to effectiveness, public hearings and the parliamentary committee can be evaluated as rather ineffective. Franz Seifert suggests that the mandatory hearings did not succeed in including the public within the institutional framework but instead they "turned into demonstrations of the rejection of genetic engineering in agriculture in general" (Seifert, 1997, p.18). Hence, it was public outrage[20] (expressed through NICP) which resulted in the governmental banning of GMOs rather than the institutionalized procedure of the public hearings.

In the case of the parliamentary committee, its failure is reflected in the citizen representatives leaving the committee They propagated that citizen participation had remained ineffective due to "insufficient proposals of the coalition parties"[21] (Weish, 1998). The final proposal drafted by the committee and submitted to the parliament for debate did not mirror the demands of the petition initiators, even though some amendments of the GTG were agreed on, such as an improved public hearing procedure, as described in the previous section (Rehmet, 2003). In sum, citizen participation in the public hearings, as well as the special committee was rather ineffective.

4.2.2 Discussion NICP

As NICP was most evident in the mobilization phase (phase II), we focus our discussion on this time period. The most important actors involved in mobilizing citizens were the two large environmental NGOs, Greenpeace and Global2000, and the tabloid paper Neue Kronen Zeitung (in short Kronen Zeitung). This widely read newspaper provided a forum for Greenpeace and Global2000 (Seifert, 2003, p.107), and strongly supported the 1997 petition. Hence, in the next paragraph, we analyze the mobilizing actors and their actions according to our legitimacy and effectiveness criteria.

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20 Meins & Bernauer (2002) outline that public outrage, "the fear or anger a risk induces in a relatively large part of a country's population" (p.6), can have a great influence on the outcomes of a conflict. While one can generally expect a highly concentrated and well-funded industry such as biotechnology, to be able to broker its interests and transpose them into law quite effectively, public outrage empowers NGOs (such as the ones channeling the protests in Austria) to gain ground in the public sphere and increase their funding, as well as their members count to tip the scales to their favour (pp.5-7).

21 Translation from "mangelhaften Vorschläge der Regierungsparteien" (Weish, 1998).

i: Legitimacy The Role of NGOs

With regard to legitimacy, we can say that the large number of mobilized citizens representing a diverse range of interests, makes the participation process representative and hence legitimate. The most notable event during the NICP mobilization phase was the popular petition in 1997, driven by an alliance of NGOs and Kronen Zeitung (Seifert, 2012, 2003). It was signed by 1.2 million citizens, representing 21% of the Austrian population. Surveys conducted right after the petition reveal even greater popular support for the cause, as 80% of the respondents stated that they endorsed the effort to ban GMOs altogether (Hoppichler, 2011, p.326). Furthermore, the protest was organized by a broad alliance of advocates of citizen interests, ranging from environmental organizations to animal rights, consumer advocacy and religious groups (Seifert, 2003). As the activist Volker Hel dorff observed, "individuals from al kinds of areas joined the protest" (Hel dorff, 2012). However, more generally, social groups with higher socio-economic status are found to be more involved in political participation than lower status groups (Rowe&Frewer, 2000 pp. 12, 13). Although in this special instance, we cannot establish that this phenomenon occurred, we must be aware that in the signing of the petition, lower income groups might have been underrepresented.

It may be claimed that the contribution of NGOs in Austria was one of channelling existing societal attitudes against GMOs. From the early 1990s onwards, public attitude was pessimistic with regard to agrobiotechnology[22] and NGOs found themselves exposed to a somewhat sensitized public (Torgersen, 2002, pp. 175). Yet, citizens' mistrust had not been clearly articulated and thus remained a vague public sentiment until NGOs took it up and amplified public concerns about agro-biotechnology. In addition, NGOs were found to be quite independent from the lobby of organic farmers which remained rather inactive during the mobilization phase (Seifert, 2012). However, NGOs' legitimacy may be limited by vested interests. Torgersen (2004) evaluates the role of environmental NGOs in Austria during the 1990s and finds that they are obscuring, simplifying and rarely even falsifying information to spark opposition to GMOs. An Austrian biotechnology scientist even goes as far as to claim rather incongruously that NGOs in the GMO debate sometimes acted like "propaganda departments 50 or 60 years ago" (Torgersen, 2004, p. 48). Consequently, it has to be acknowledged that even though they are non-profit organizations, NGOs have to act according to market rules, as they need to generate funds and are thereby dependent on conflicts, constantly struggling for public attention (ibid).

22 only 3 to 4% of the Austrian population was optimistic about gene technology in 1993 (Togersen, 2002, Figure 1, p. 176).

However, in the case under scrutiny, the NGOs' pursuit of their individual interests was to a large extent in line with common public interests, which indicates that they acted upon a certain basis of legitimacy.

ii: The Role of the Press

In this section, we evaluate the legitimacy of the second influential actor in the process of NICP, the newspaper Kronen Zeitung. The Kronen Zeitung is by far the most read newspaper in Austria since its daily issues reach one in two Austrian citizens (Der Standard, 2010). The large readership of the newspaper points towards the large extent to which many Austrian citizens' views are represented in the Kronen Zeitung. As a civil servant from the Austrian Ministry of Trade put it, many observers think that in Austria "the public is the Kronen Zeitung" (Torgersen & Bogner, 2004, p. 49). Furthermore, they provided a forum for NGOs and citizens to voice their opinions on the issue of GMOs (Eichinger, 2008, pp. 4-6; Wagner, 1998, p. 19). Similarly to NGO involvement, the Kronen Zeitung's mobilization campaign allowed for the representation of a diversity of interests, from environmental to animal rights and religious groups and beyond. Hence, we may say that the Kronen Zeitung's mobilization does indeed represent the interest of the majority of citizens. Formally, the Kronen Zeitung has the status of an independent news publisher[29]. The own interest of the Kronen Zeitung is to have a far-reaching circulation of its newspaper. Hence, in order to attract the public's attention and to increase their run, the Kronen Zeitung uses a highly populist and scandalizing style of reporting. As former ÖVP party leader Erhard Busek explains: "the Kronen Zeitung always bases their discussions on emotions with a view to sales and as such, with the people and for the people" (ARTE, 2002). With regard to the GMO controversies, we can say that it offered a platform for common public interests to be voiced and amplified. However, due to its wide-spread circulation the Kronen Zeitung also effectively shapes public opinions and interests. According to Pierre Bourdieu, people do not *have or form* an opinion and interests but they *take* a position from a set of pre-formulated opinions (1972). In our case, the Kronen Zeitung began their coverage of GMOs with the scandalization of the unauthorized GM-potato release in 1996. For many citizens this was the first time that they were exposed to the issue of biotechnology: although Austrians had a vaguely pessimistic attitude towards GMOs prior to this event, the issue had not been highly visible in the public sphere. Hence, we may say that the Kronen Zeitung filled this public opinion vacuum on biotechnology and imposed its views on the issue on a large number of people (Wagner et. al., 1998, p.19). Whereas on the one hand, the Kronen Zeitung represented public interests, on the other hand it also actively shaped these interests.

In sum, the Kronen Zeitung, due to its wide-spread circulation, can be seen to give an account of and potentially represent the views of almost half of the Austrian population. However, this is only completely true if we regard public interests and opinions as pre-constituted. When we discussed the legitimacy of the Kronen Zeitung, we found out that though the paper's interests were seen to be in line with common interests, they also effectively influenced citizens' interests and opinions. Thus, there are arguments for a positive as well as a negative evaluation of legitimacy of the Kronen Zeitung.

In conclusion, NICP as mobilized by an alliance of large NGOs and the Kronen Zeitung may be evaluated positively as well as negatively on grounds of legitimacy. On the one hand, the alliance took up and amplified the vaguely pessimistic attitude towards GMOs in Austria which echoed the concerns of a large number of Austrian citizens from diverse groups. On the other hand, people's attitudes on GMOs were also effectively influenced by the Kronen Zeitung and NGOs amplifying their demands through populist coverage of this tabloid.[23]

iii. Effectiveness

Although the popular petition in 1997 did not legally require the government to act, Franz Seifert (2012) observes a direct, political effect of the anti-GMO campaign, mobilized by the alliance of NGOs and Kronen Zeitung, on Austrian GM-policy. As outlined above, the Austrian government modified the GTG according to some of the demands of the protesters with regard to legal standing, liability and punishment for breaches. Second order effects were the blocking of official, contained cultivation experiments, especially those commercially motivated and more generally any cultivation of GMOs[24].

According to Seifert, the antiGMO campaign and the petition in 1997 left the Austrian government without many alternative policy choices than to "find ways to politically implement this total aversion against genetic engineering" (Seifert, 2012). The implementation was completed in 2000 and since then, the Austrian government has tried to ban agro-biotechnology from the country. Furthermore, Seifert claims that NICP had also motivated Austria to propose changes on EU law allowing for socio- economic opt-outs (ibid.). At the same time that Austria followed the protesters' demands, NICP slowed down. According to Seifert, Torgersen and Bogner, the anti-GMO protests were highly successful in pressuring Austrian politics to follow suit (Seifert, 2012; Torgersen & Bogner, 2004, p.16).

23 Due to the limited scope of this article we cannot carry out an in-depth qualitative analysis of the newspaper's previous work, which means that we must leave the foregoing evaluation unrated.

24 2003: 108; Protocol of the parliamentary session.

Nonetheless, we must note that we cannot *conclusively* determine causality between demonstrations and outcomes. An alternative or complementary explanation of the policy changes on agro-biotechnology by the Austrian government that should not be neglected, is that the shift happened in order to establish a market niche as a GM-free seed- and food-producing and exporting country in Europe. The large and powerful Austrian Farmers' Association (Österreichischer Bauernbund) that is closely aligned with the then ruling party ÖVP, supposedly changed its opinion towards a negative stance on agro-biotechnology in the late 1990s and thus enabled the ÖVP to join in the anti-GMO stance (Seifert, 2012). This change was likely to be due to economic reasons, as Seifert argues that the industrial agricultural producers in the association noticed that agro-biotechnology did not fulfil its promises of increased profit for farmers, and that GM-free products may allow for a market niche to be filled (ibid.). In sum, whereas there are alternative explanations for the described political changes that allow for further exploration, based on our research, we assume that NICP did have an effect on political outcomes and probably a quite strong one, as Austrian politics to a large extent fulfilled the protesters' demands.

4.3 Conclusive Interpretation of Case Discussion

In this section, we use the results from the foregoing analysis to discuss our hypotheses established prior to the case analysis. Our first hypothesis was that *ICP is more effective than NICP.* The analysis of GMOs in Austria showed that his was clearly not the case. Whereas, ICP was not very salient around agrobiotechnology and also not very effective in influencing policies, NICP was likely to have had a strong impact on the change of the policy discourse in Austrian agro-biotechnology politics.

Our second hypothesis was that *ICP is more legitimate than NICP*. The analysis showed that this cannot be straightforwardly answered but that we need to highlight the complexities of legitimacy in ICP and NICP. Both ICP and NICP fulfil and lack certain dimensions of legitimacy. With regard to the analysis of ICP in Austria, we can say that ICP aimed at fulfilling the representativeness criterion, as in the case of public hearings anyone could voice complaints and the initiators of the popular petition were invited into the parliamentary special committee. However, in reality, citizens were underrepresented in the latter, and, as observers have noted, the officials in charge took little or no note of their propositions with regard to both the matter at hand and larger agenda issues. In the public hearings, similar treatment of popular concerns was noted. This renders both the representativeness and independence dimension of legitimacy of ICP rather questionable.

Concerning the analysis of NICP in Austria, we may say that NICP can be evaluated positively due to the mass of participants (1.2 million) that signed the popular petition of 1997. However, NICP lacks legitimacy since there are insufficient control mechanisms and objectivity. Actors such as NGOs and the tabloid press were crucial in picking up, amplifying, expressing and forming citizens' demands, e.g. by calling for the petition and organizing demonstrations.

In sum, our case analysis of citizen participation in Austria around agro-biotechnology shows that NICP is likely to have been much more effective in comparison to ICP, whilst ICP was relatively legitimate on grounds of representativeness yet lacked legitimacy on grounds of independence. NICP was very visible and most probably effective, yet hardly legitimate beyond doubt.

5. Conclusions

In this article, we deal with the phenomenon of ctizen participation in national risk governance. We make a distinction between institutionalized and non-institutionalized citizen participation and assess participation according to legitimacy and effectiveness criteria. In our case study, we focus on the controversy around agrobiotechnology in Austria. Our analysis shows that, ICP was not well implemented and thus, neither very legitimate nor effective. NICP, on the other hand, was to some extent legitimate and effective. In the ideal case of ICP there is both high legitimacy and high effectiveness, which reflects the need to find ways of adequately implementing more ICP measures. As we have identified in our case description, EU legislation limits ICP mechanisms in the Member States to discussions on health and environmental safety grounds. In order to allow for citizens to genuinely voice all their concerns through ICP, there is a need for ethical and socio-economic arguments to be considered a valid basis of argumentation. This is merely one specific example drawn from our case study, which corroborates that paying attention to NICP measures can substantially improve ICP measures, as well. However, it is imperative to note that even if ICP was perfected and better implemented, it would remain incomprehensive. Issues that become salient to the public and are neglected by regulators in their agenda, can only surface through NICP, as they can hardly be planned. The regulation of uncertain risks in particular carries the inherent problem that the effects of a product authorization still bear some uncertainty at the point of time when the first regulatory steps are taken. The issue of GMOs in Austria shows that the public protests deviated from the original assessments performed by scientific committees in that they reasserted non-

biotechnological repercussions of GM products. The agenda for regulation had already been set at this point of time, and its limitations had to be challenged from the outside, i.e. by NICP. Whereas ICP allows citizens to have a voice within the policy process, there is always the danger that citizens are co-opted by political elites and hence, emancipatory policy-making is hampered with. The absence of institutional constraints is exactly the strength of NICP, as only outside the scope of the political system, strong counter-politics can develop that may formulate alternatives to the status quo instead of only modifying it. On the other hand, the legitimacy and measurable effectiveness of ICP are a complementary part of citizen participation. To shield participation from particularistic interests, misrepresentation, and misinformation, ICP remains the most valid means. Concerning the legislature, turning more attention to ICP for agenda-setting and formulation of law, and NICP for the responsiveness of law to new popular demands, could help to increase the sustainability and perceived normativity of legal acts with regard to the regulation of uncertain risks.

In our work, we only focused on one country. This means, though we believe that some of our findings are generalizable, they are highly inductive. Consequently, we would like to encourage similar case studies in other European countries to add to our conclusions. Further, we also recommend to pursue more in-depth studies of NICP to add to the debate on inclusive policy-making and increase applicability, especially through the refinement of our legitimacy criteria.

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Risky Business

How NGOs Use and Gain Scientific Knowledge in the Context of GMO Risk Regulation

Lisa Albers, Bob Jennekens, Constanze Müller, Hjørdis Petersen, Natascha Spörle

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1. Introduction

> *"Our inability to predict with certainty what might happen when [genetically modified] plants are released into the environment strengthens the hand of those who wish to stop all uses of gene cloning in plant breeding"*
> *– J.E. Beringer, 2000, p. 209*

Food is indispensable to our survival and part of our daily lifestyle. Whilst being traditionally perceived as something essentially natural, foodstuff has always been modified through breeding to meet human needs. Without doubt, the latest development in this age-old tradition to 'change' the original state of nature is genetic engineering; arguably one of the most controversial scientific achievements of recent years.

Genetic engineering refers to the alteration of the genetic material of an organism's genome and is propagated as one of the biggest advancements in science, and agriculture in particular. Genetically modified organisms (GMOs)[1] are argued to tackle societal problems such as a rapidly growing world population or climate change by allegedly enhancing the efficiency of conventional agriculture. However, throughout various regions of the world, and in Europe particularly, the 'genetic revolution' is often met with caution, not to say outright resistance. Indeed, genetic modification as such has triggered an ethical debate, supporting general doubts about the safety of GMOs.

Within the perceived constant battle between nature advocates and industry, the European Union (EU) is the final decision-maker regarding GMO-authorisation[2] engaging in risk-regulation. Hereby, the EU employs almost exclusively natural scientific evidence provided by the European Food and Safety Authority (EFSA) to decide about the safety, and consequently, about the permission to cultivate a GMO. Thus, science appears to be the hallmark of the EU decision-making apparatus. Indeed, European decision-making is based on the precautionary principle that prohibits the usage of GMOs in case it implies the potential risk to cause harm to the environment or public health. The enhanced

1 GMOs of the first generation are modified to be toxic against their pests. GMOs of the second generation have been modified to include certain vitamins or nutrients. As experiments with GMOs of the second generation have remained largely unsuccessful, only GMOs of the first generation have been authorised for cultivation.

2 Regulation (EC) No 1829/2003 and Regulation (EC) No 1830/2003.

role of science relates back to today's general risk aversion, and a perception of science to provide ultimate answers to the concerns of mankind (Irwin & Wynne, 1996; Ravetz, 2004). However, this is highly problematic as scientists are expected to deliver certainty information in situations where no scientific certainty can be given (van Asselt, Vos, 2008), for example, regarding long-term effects of GM-food on human health.

Scientific uncertainty is intensified because, given the highly controversial nature of the issue, opposing lobby groups try to influence the EU by presenting different information to support their respective claims. Thereby, they base their argumentation on different interpretations of the notions of 'risk' and 'uncertainty' (Jasanoff, 1997). One of the most crucial actors among the involved lobby groups are non-governmental organisations (NGOs), which try to introduce their, often very specific, expertise in the EU decision-making process. NGOs generally oppose genetic engineering and traditionally justify their opposition to GMOs on moral or ethical grounds.

However, the fact that scientific evidence seems to be a precondition to be able to influence EU policy making clashes with the public perception of NGOs being rather ethical proponents instead of actors basing their argumentation on science (Bieri, 2010). At the same time, NGOs are frequently accused of being "anti-science" (Lynas, 2013) or un-scientific, therewith implying that they have no legitimacy to influence the policy making process due to their alleged bias and partiality when dealing with GMOs. It is, thus, of a high relevance to examine in what way NGOs make use of scientific knowledge to justify their opposing stance towards GMOs. Our research is based on a case study of seven different NGOs and focuses on their publicly available communications. Therefore, this paper examines how NGOs:

1. *Use* scientific knowledge
2. *Gain* scientific knowledge

The research is motivated by the blatant lack of academic literature on this issue. Indeed, the existing literature mainly focuses on the influence of NGOs on the decision making process or questions the scientific expertise of policy makers. However, the usage of science by NGOs has almost entirely been neglected. As the approach of this paper is pioneering in nature it aims to map the variety, examining how different NGOs have different ways of employing scientific knowledge. Herein, we claim that NGOs do indeed use scientific knowledge. Thus, we find that al egations of NGOs being 'un-scientific' in their argumentation to support their contra-GMO stance do not hold. In contrast they apply high academic standards regarding their references and argumentation. Moreover,

we confirm the assumption of Jamison (1996) that scientific knowledge is deployed from an interdisciplinary background. We also argue that the reasons and, ultimately, the consequences of NGOs using science to back up their claims might eventually affect their role in policy-making as well as in society.

This paper first introduces the reader to NGOs and the European risk regulation procedure within a topic characterised by a high level of uncertainty, namely GMOs. In this context it outlines the dilemma to science-based decision making. After considering the broader role and involvement of NGOs and scientific experts in the policy making process, we proceed to test the claims that have been made in the literature in a comprehensive case analysis of seven NGOs. We particularly focus on the way they use natural-scientific information and also incorporate their usage of social-scientific arguments. Lastly, we involve in a taxonomy, generalising our findings to a higher level and developing ideas for further research.

2. Setting the Stage: The Role of NGOs in EU-Risk Regulation

Within the European Union, the development and authorisation of GMOs continues to be surrounded by controversy and often polarised debates due to uncertainty issues that are associated with genetic engineering (Everson & Vos, 2008). The fact that potential effects of GMOs on the environment and human health remain unpredictable continues to fuel heated debates on the safety of GMOs, for example when employed in conventional agriculture. Indeed, the uncertainty with regard to long-term benefits and risks of GM-crops is expressed in substantially different risk perceptions.

On the one hand, risk is perceived to be minimal and greatly outweighed by the potential advantages of GM-crops such as enhanced benefits to farmers and consumers in the form of increased supply and lower prices for foodstuff, a higher plant resistance to crop pests and a consequently reduced usage of pesticides (Carrington, 2012). In this context, it is claimed that the current debate surrounding genetic engineering suffers from an "[...] overemphasis on what might happen [...]" (Beringer, 2000, p. 213) and that uncertainty per se does not constitute a legitimate reason to ban GMOs. Further, it is argued that a high public demand for security might be counterproductive in the long-term by potentially obstructing scientific progress (Douglas & Wildavsky, 1982; Wildavsky, 1991).

On the other hand, uncertainty could be equalised with potential risk, giving rise to the argument that as long as there is no certainty about the safety of genetic engineering, it is

irresponsible to cultivate GM-crops. Arguably, this position persists in Europe today, as public perception regarding GMOs is defined as risky, due to their potential negative consequences on public health and the environment – despite the lack of an ultimate scientific proof of the harmfulness of GMOs (van Asselt & Vos, 2008). Nevertheless, issues of food safety, genetic contamination and, not least, doubts about the ethical legitimacy to 'mess around' with the uniqueness of nature are frequently brought up as counter- arguments to genetic engineering (Wynne, 2001; Wal s, O'Riordan, Horlick-Jones & Niewöhner, 2005).

The result is a dilemma concerning the benefits of GMOs in terms of innovation and technological progress on the one hand and potential dangers of genetic engineering with regard to uncertainty and safety concerns on the other. This dilemma renders the process of risk regulation complicated. These difficulties become pressing in particular on the EU level as it is characterised by a complex supranational process of policy-making within a multi-level governance setting (van Asselt & Renn, 2011). Herein decisions have to be taken by consensus among twenty-seven – soon twenty-eight – Member States, which all have potentially different stances on the issue of GMOs, and varying interpretations of 'risk' and 'uncertainty'.

Van Asselt and Renn (2011) define the process of risk regulation as "the various ways in which many actors, individuals, and institutions, public and private, deal with risks surrounded by uncertainty, complexity, and/or ambiguity" (p. 432). Within the process of GMO risk regulation on the EU level, the actors can be classified into four main groups (van Asselt & Vos, 2008). First, the 'risk producers' are the actors that pursue "potentially hazardous activities or technologies" (ibid, p. 283). One of the largest risk producers world-wide in regard to GMOs is Monsanto, a major biotechnology company, active in producing and marketing GMOs such as MON810, a specific GM-maize that includes an artificially inserted gene to avert pest infestation.

Second, 'risk managers' primarily include the European Commission, the Council and national authorities, thereby uniting the actors that are responsible for decision- and policy-making on GMO issues (ibid). Given the fast technological and scientific progress, which often causes new risk potential, risk managers face increasing challenges in terms of scientific assessment and regulation (Levidow, 2005). At the same time, the increasing public demand to ensure the safety of public health leads policy- makers to base their decisions on scientifically sound facts (Douglas & Wildavsky, 1982; Irwin & Wynne, 1996). Thus, to compensate their shortcomings in scientific knowledge and to assure the public of the safety of scientific innovations, policy-makers have to rely on scientific expertise. Policy thus comes to be justified through "science-based decision-making" (Everson & Vos, 2008, p. 8; Brown, 2009).

Scientific experts constitute the third group in the EU risk regulation process: the 'risk assessor'. When examining the potential risks of GMOs, the role of the risk assessor is assumed by the EFSA and its special GMO-panel (van Asselt & Vos, 2008, p. 283). The emergence of 'science-based decision- making' in EU policy-making is specifically linked to the nuclear catastrophe in Chernobyl as well as the outbreak of the mad-cow disease (BSE or *Bovine Spongiform Encephalopathy*) in the 1990s, when the failures of politicians and wrong scientific assessments led to an increased public sensitisation with regard to the benefits and risks of scientific innovations and resulted in a redefinition of the public's perception of science (Irwin & Wynne, 2004). Today, EU policy-making is, thus, largely based on the precautionary principle to "legitimate [...] decisions and actions in situations characterised by uncertainty" (van Asselt & Vos, 2006, p.314; Löfsted, 2008; Steffek & Nanz, 2008).

However, science-based decision-making brings a highly complex issue to the fore. Demanding science to deliver certainty statements on issues characterised by uncertainty and potential risks constitutes a contradiction in itself; and thus, has been referred to in the literature as the *uncertainty-paradox* according to which "[...] authorities resort to experts for conclusive evidence and definite answers, despite uncertainty precluding both conclusiveness and definitiveness" (van Asselt & Vos, 2008, p. 282; van Asselt and Vos 2005, 2006). The quest for definite answers is often translated into almost zero risk tolerance with regard to scientific innovations, which poses great problems to scientists and is often criticised by risk producers (Irwin & Wynne, 2004).

Nevertheless, policy-makers remain dependent on experts in risk governance. In this respect, Everson and Vos (2008) emphasise that "uncertain risks not only reveal the limits of science but also unveil their political character as a wider public perceives that those hazards could impact negatively upon society and therefore demand that some political action be taken by political actors" (p. 11). As decision makers aim to retain some democratic control over the expert knowledge on which policy- making is based upon, the *scientisation of politics* adversely leads to a *politicisation of science* (Beck, 1992; Latour, 2004; Weingart, 2001). Put in more theoretical terms, science and politics – as well as the bodies representing each – are inseparably intertwined and characterised by their interdependence (Latour, 2004).

Finally, 'risk protesters' who oppose "new technologies or activities on behalf of potential risk victims" (van Asselt & Vos, 2008, p. 283) constitute the fourth actor group within the GMO-risk regulation process. With regard to the GMO debate these are mainly non-governmental organisations (NGOs) such as Greenpeace or Friends of the Earth (FoE). Ruzza (2004) identifies NGO s acting on the EU level as "public-interest associations" (p. 3) since they advocate overarching societal interests.

Traditionally, NGOs have emerged as a 'voice of the public' in acting as a 'watchdog' on policy-makers in different issues of socio-economic and public concern, notably the environment (Bieri, 2010). As a consequence, they essentially derive their legitimacy from their claim to act on the grounds of public interest and often present themselves as some kind of moral, uncorrupted authority. Thereby, NGOs represent groups or topics that have long been marginalised or underrepresented in the political arena, such as political minorities, the environment or animal rights (Piattoni, 2010). Furthermore, they can act as independent suppliers of information. The Europe 2020 strategy recognises them as stakeholders of civil society and vows to enhance working relations between institutions and NGOs, especially by means of the European Commission's advisory bodies (European Commission, 2010).

Despite that, NGOs are not recognised as formal or legal participants in the policy-making process. Whilst the systems of the United Nations and the Council of Europe allow for an official NGO consultative status, the European Commission, as Bouget & Proteau (2002) point out, "rejects any official accreditation because it wants to maintain as open a dialogue as possible" (p. 34). Indeed, the European Commission (2000) emphasised that a legal basis for consultation and dialogue with NGOs does not exist. This position has not changed over the last thirteen years and has prevailed throughout the last Treaty changes (Treaty of Nice and Treaty of Lisbon).

Nevertheless, whilst NGOs might not be recognised as official participants in the policy-making process, they are crucial stakeholders on the EU-level. The European Commission (2000) has gone so far as to emphasise that they have the potential to consolidate a "participatory democracy" (p. 4) within the EU, thereby enhancing the role of NGOs by not only regarding them as a necessary evil, but increasingly accepting them as representatives of civil society to participate in the policy-making process (Bieri, 2010). The European Commission (2000) clearly admits NGO involvement in the EU policy making process since it underlines that NGOs contribute to legitimise the EU among its citizens due to their inclusion into policy shaping and implementation.

In fact, NGOs are in close contact with the European Parliament and dialogue with the European Commission takes place on a regular basis, being an "important complement to the institutional process of policy shaping" (p. 7). NGOs are, for example, invited to contribute their expertise in advisory committees, hearings and events on GMO risk assessment and regulation. Moreover, they participate in ad hoc as well as official meetings (ibid.; Brown, 2009). Additionally, many NGOs receive financial support from EU funds, further underlining the close-knit relationship between risk protesters and risk managers (European Commission, 2000). These institutional provisions underline the essential role of NGOs for EU policy-making and explain why NGOs constitute one of the most powerful

external actors in the policy-making process. In that they possess the potential to influence policy-making, involved NGOs give rise to a system of organised civil society and interest representation on the highest level of policy-making (Heard & Lauréote, 2008).

Besides their involvement in the policy-making process, NGOs have further assets, especially when the issue at stake is scientifically disputed and characterised by a high level of uncertainty. By issuing their own information or pointing out uncertainty, they can construct an independent narrative, thereby constituting an alternative information provider that has the ability to raise awareness among policy makers, other stakeholders and the public. Accordingly, as Jasanoff (1997) illustrates: "NGOs may usefully open up the debate [involving governments, industry and the public] either by questioning prevailing expert opinion or by expanding the available information base" (p. 581).

However, NGOs have frequently been criticised by other stakeholders, denying them recognition as credible partners on the basis of them allegedly issuing highly biased opinions by framing their narrative in a strongly emotional and irrational way without referring to scientific sources to back up their claims (Wynne, 1996). This debate about the al eged 'pseudo-science' pursued by NGOs often mounts into accusations that NGOs run a "hysteria campaign" (Entine, 2012), irresponsibly exploiting civic concerns (Douglas & Wildavsky, 1982; Lynas, 2013).

Indeed, these accusations have sometimes been fuelled by NGOs themselves when criticising the role of experts, experts' opinion, or when questioning scientific facts (Brown, 2009), particularly in the debate surrounding GMOs. However, even though NGOs tend to criticise the role of experts and science in general, they have, as Jasanoff (1997) argues, "recognised that scientific knowledge is potentially one of their strongest al ies" (p. 581). Thus, one could picture NGOs using science as a tool – like one uses a hammer to drive in nails – and expert knowledge is just one tool in the NGO's toolbox.

However, whereas the literature, mainly dating from the late 1990s, seems to agree that NGOs use scientific knowledge, it has not been discussed in what particular way they do so. Yearly (1996) has focused on environmental groups such as Greenpeace and Friends of the Earth, coming to the conclusion that they do use science. Jamison (1996) additionally examines where NGOs gain scientific knowledge from; arguing that NGOs draw their scientific knowledge from an interdisciplinary background of natural and social sciences, combining the two to a "human ecology" (p. 241). However, neither Yearly nor Jamison engage in a thorough case analysis of how scientific knowledge is gained and used in practice. Therefore, this paper addresses this gap in the literature and aims to contribute to the academic discussion by examining to what extend NGOs employ, process and refer to science regarding GMOs and potentially related risks.

3. Yielding the Tool: Scientific Knowledge in the GMO-Debate

This chapter analyses how NGOs use scientific knowledge and where the scientific knowledge used is retrieved from. To this end, the analysis is based on thirty-six written publications[3] by seven different NGOs: Greenpeace EU Unit, Friends of the Earth Europe (FoEE), the International Federation for Organic Agriculture (IFOAM EU Group), the European Consumers' Organisation (BEUC), Corporate Europe Observatory (CEO), European Coordination Via Campesina (ECVC) and the European Community of Consumer Cooperatives (Euro Coop).

This selection of NGOs is based on several criteria. Firstly, a chosen NGO has to operate on a European level considering that GMO-regulation and authorisation is primarily a task of the European institutions. Thus, an analysis of international NGOs, such as Greenpeace, FoEE and IFOAM, only includes those publications issued by the respective European branch. Second, all selected NGOs address the GMO debate. Third, despite a broad topic convergence, the NGOs analysed differ in size, prominence and working practices. Fourth, the chosen NGOs might work within a specialised field of expertise – e.g. IFOAM EU Group focuses on organic agriculture, whilst BEUC is primarily active in consumer protection. Regarding the selection, it must be recognised that the seven NGOs can only offer a limited picture. Nevertheless, they can be regarded to be representative of their branch of organisations as they map the variety of working practices, specialisation and visibility of NGOs.

Similarly, the choice of analysed publications is based on the premise to address the variety of the output of NGOs. In their role of risk protesters, NGOs contribute to the policy-making process and to public debate via multiple means of communication methods. Next to active (street-) campaigning, NGOs also make use of written publications to present their point of view. Today, internet output and social-media presence constitute one of the most important means to connect to an (international) audience. It can thus be assumed that NGOs issue various types of publications, depending on purpose and intended audience. For instance, open letters tend to be shorter and more concise, based on the intention 'to make a point', equally accessible to experts and the lay public; whilst detailed reports on (specific) GMOs can comprise several pages and are often kept in a highly professional format. Thus, assuming that NGOs produce publications for different

3 Publication is defined as all publicly available means of communication of NGOs, comprising reports, web page articles, (media-) briefings, position papers and one power point presentation

purposes, it is hypothesised that the use of scientific knowledge might differ with regard to the type of publication. Accordingly, the thirty-six analysed publications are very diverse and comprise detailed reports, (media-) briefings, position papers, web page articles and official communications to the European Commission.

To further account for variety, the content of the publications is analysed, based on the assumption that NGOs cover the GMO issue in different ways: whilst some might focus on specific cases of GMOs, others might simply address GMOs and genetic engineering from a broader perspective. To make case-specific publications more comparable we chose to focus exclusively on publications covering the GMOs MON810 and Bt-11.[4] Indeed, covering not only a wide range of NGOs but also different kinds of publications with differing content allows for a comparison and, to a certain degree, a generalisation of our findings. Nevertheless, the choice of NGOs and publications remains limited and can only offer a first insight into how NGOs use scientific knowledge. Thus, it is necessary to interpret the findings cautiously.

As it is the objective of this paper to find out how NGOs use scientific knowledge, we identify all scientific claims about GMOs within the chosen publications. Herein, 'scientific claim' is defined as a statement that is verified by natural sciences.[5] This choice of definition was motivated by the fact that European policy makers base their decisions on natural sciences and on the opinion of natural scientists, the risk assessors in risk regulation (Van Asselt & Vos, 2008). Subsequently, the identified scientific claims were qualitatively analysed and coded according to three categories. While the main findings are illustrated numerically, we strongly emphasise that this paper does not engage in a quantitative analysis. Rather, this paper conducts a qualitative analysis in quantitative terms.

The first category ('no references') comprises scientific claims, which are not based on any evidence or references including, for example, claims that are not supported by any academic reference. The second category ('explicit references') contains statements that are based on explicit references to scientific knowledge or scientific experts, thereby adhering to the same high standards of referencing that are required for academic publications. Finally,

4 Both MON810 and Bt-11 are specific GM-maize, modified with a gene retrieved from the Bacillus thuringiensis (thus the name Bt-maize), which produces a toxic able to kill pests, such as the European corn borer. MON810 is produced by the American company Monsanto, while Bt-11 is produced by the Swiss company Syngenta.

5 Without attempting to define what 'proper' science is (usually defined according to Karl Popper's falsification criteria), this article employs the following definition of the Oxford Dictionary of natural sciences: "a branch of science which deals with the physical world, e.g. physics, chemistry, geology, biology".

the third category ('general references') refers to scientific claims, which fall in between the two extreme categories. This would hold for example for claims, which make a reference that is only indicated as a footnote without mentioning the study in the text.

We are aware that any categorisation might implicitly contain a grading as to which kind of statement is desirable and which one is not. However, this paper does not involve in a discussion on the quality of academic vis-à-vis non-academic references. Instead, we deem a science-based analysis as most appropriate to scientifically analyse claims about NGOs allegedly pursuing a non-scientific structure of argumentation. Furthermore, the categories solely cover references to natural sciences, which by no way intend to claim the superiority of natural sciences over social sciences. With regard to the categories, further limitations include that the broad classification scheme remains relatively simplistic and, at best, constitutes a first phase of research. Nevertheless, it offers a useful impression of how NGOs use scientific knowledge.

As already mentioned, the categorisation of scientific claims into the aforementioned three categories limits the analysis to references to natural sciences. However, social sciences should not be disregarded, especially because Jamison (1996) has argued that NGOs use an interdisciplinary approach of science to justify their claims. Thus, a reduced focus on only natural sciences or only social sciences respectively would yield at best a limited picture of how NGOs use scientific knowledge. As social sciences are more difficult to map numerically, this paper engages in a two-folded consideration of the social sciences. First, in light of the current socio-economic environment in the European Union, we analyse how NGOs use economic reasoning in their argumentation. This choice is based on the premise that currently policy makers as well as the public are more likely to be sensitive to economic reasoning, than in times of economic well-being. Thus, we expect NGOs to address issues of socio-economic importance in their argumentation.

Second, the paper chooses to focus on the *concept of uncertainty* – counting the references made by NGOs to this concept. This choice is based on its prominence amongst scientists and policy makers, by for example constituting the basis of the precautionary principle (Van Asselt & Vos, 2006). Therefore, it is relevant to analyse if NGOs recognise this uncertainty and if so, how they refer to it. This paper hypothesizes that NGOs do employ both science and the concept of uncertainty supporting their agenda, just as any other participant in risk regulation (Jasanoff, 1997; Yearly, 1996). The following three sections closely examine the generation and usage of scientific knowledge according to different NGOs.

3.1 Greenpeace Europe

"Many of the global problems we face can only be detected and understood through science" – Greenpeace, 2009c

Greenpeace is one of the largest and most active NGOs concerning environmental issues. It is active on a global scale, well-known to both policy-makers and the public and addresses a great number of topics related to environment and animal protection. Greenpeace is highly involved in the GMO debate and strictly opposes the development of any GMO variants concerning animals, plants and foodstuff. Consequently, it promotes 'green', 'clean' and 'safe' agriculture and demands a moratorium on the use of genetic engineering. Greenpeace's EU Unit is actively involved in the policy-making process by participating in European Commission ad-hoc and regular advisory committees. Thus, it can be considered to be one of the most relevant *risk protesters i*n Europe.

Within the analysis of how Greenpeace 'uses' and 'gains' scientific knowledge in its overal risk communication on GMOs, we have mainly examined publications which refer to the specific GMOs MON810 and Bt-11, but have also included publications on GMOs in general. The analysis of the latter is based on web page articles, a briefing document (Greenpeace 2011a) and a technical note, which was drafted in cooperation with FoEE (Greenpeace, FoEE, 2009). Further, we have identified four publications that cover either MON810 (Greenpeace 2009d; Greenpeace, FoEE 2009) or Bt-11 (Greenpeace 2005; Greenpeace 2009a). While the number of analysed publications is limited, the selection indicates that Greenpeace does not only focus on GMOs in general but also participates in the discussion about specific GMOs – thereby indicating that larger NGOs have the means to commit themselves also to specific topics in the broader discussion surrounding GMOs.

Throughout all analysed publications we have identified sixty-nine scientific claims out of which forty used explicit references, nineteen general references and ten no references (See Graph 1). Thus, only 14.5 per cent of all scientific claims were not supported by any references. Consequently, before engaging in a more detailed analysis, it already becomes clear that the claim that NGOs do not use scientific sources cannot be supported by our findings. Nevertheless, one can observe differences between the publications specialised in specific GMOs and publications covering GMOs more in general. Whereas publications on MON810 and Bt-11 entail thirty-seven explicit references, publications covering GMOs in general seem to reference less explicitly. Within the latter, only three scientific claims were supported by explicit references. However, only one entailed no reference at all, whilst a total of twelve scientific claims contained general references. It

follows that general publications might be considered to be less scientific or academic, but cannot be argued to be unscientific in terms of including no scientific references at all.

The numbers have to be considered with some caution for three reasons. First, the structure and style of the Greenpeace articles vary considerably which makes a generalised conclusion harder. For example, the analysis comprises a lengthy research report on Bt-11 entailing extensive background information (Greenpeace, 2005), a rather short and precise document entailing technical comments (Greenpeace, 2006), and a briefing with the format of a public statement (Greenpeace, 2011). One could argue that these different styles depict the two-faced role of Greenpeace very well: on the one hand, as a professional environmental organisation that has a considerable political influence and that is trying to produce output on a high scientific level; and on the other hand, as an NGO engaging with society on a campaigning and advocacy level.

Second, the different publications do not always address the same audience; therefore, varying in their extent to use explicit scientific references. Web page articles, for example, are mostly intended to be read by the general public, which is why complex scientific sources in the form of explicit references are rather avoided. Last, publications, which cover a specific GMO, can fall back on a much greater range of scientific studies focusing on that GMO. This relates to the fact that every GMO is constantly assessed not only during the process of invention but also during the various complex authorisation processes across the world.

The numbers have already indicated how important science seems to be for Greenpeace within their argumentation. It appears that Greenpeace is well aware of their usage of science and of them being referred to as unscientific. As Greenpeace (2007) emphasise on their international website:

> "[...] science is used to justify the existence and deployment of environmental threats, as nuclear power and genetically modified organisms Our opposition to these technologies has led to accusations that Greenpeace is 'anti-science'. This is far from the case. We depend on science and technology to provide solutions to environmental threats".

Indeed, in a briefing document Greenpeace (2011) goes even further, outlining that they do not only depend on science - as mentioned above - but that they themselves provide "scientific evidence" (p. 1). Thus, Greenpeace does not only retrieve scientific knowledge from external sources but independently engages in producing scientific studies.

To escape the dependency upon science produced by third parties, Greenpeace, in 1987, has established a separate Science Unit in cooperation with the University of London

(Greenpeace, 2009c). This underlines that Greenpeace highly values independent scientific knowledge. The Science Unit aims to "provide scientific advice and analytical support to Greenpeace offices worldwide, over a range of disciplines" (Greenpeace, 2009e). However, as the Science Unit cannot be assumed to be equipped to cover al fields of scientific research, they "commission many scientific research reports and investigations to support [their] campaigns" (Greenpeace, 2009c). Thus, Greenpeace retrieves scientific knowledge from multiple sources, providing not only a basis for their own scientific research but also supporting the establishment and search for scientific solutions on an international level.

It seems that Greenpeace sets quite high standards on the scientific knowledge used. It can be assumed that this relates to the fact that Greenpeace has often criticized 'mainstream' scientists, scientific statements, European risk producers, assessors and managers for being one-sided, for example by developing and publishing scientific studies that seem to support the pro-GMO argumentation of the food and agriculture industry. For example, in context of the authorisation of Bt-11, Greenpeace clearly stated that they had doubts about the quality of "the data provided by Syngenta and the assessment of the EU's Scientific Committee on Foods" which apparently referred to "outdated rules" (Greenpeace, 2004). Greenpeace backed these claims with research conducted by the French Food Safety Authority, the Belgian Biosafety Council and the Austrian Federal Environment Agency.

Additionally, Greenpeace (2011) claims that the European Commission, as risk manager, does not "provide scientific evidence on the environmental safety of GM plants" (p. 2). Moreover, Greenpeace denounces that there is a clear lack of independent scientific studies provided from the side of the EU that could predict the effects of GM crops (ibid). Thus, while Greenpeace themselves attempt to base their argumentation on explicit scientific sources, they accuse the risk managers of using too little, if any, scientific references.

In another report, Greenpeace (2005) criticises EFSA's notification on Bt-11 for "lack[ing] original data that would enable an independent assessment" (p. 3); thereby, EFSA implicitly denies the negative impact of Bt-11. In this regard, Greenpeace argues that EFSA's notification dossier does not mainly present original data from studies, but rather presents summaries and that thus, the notification cannot be considered as a clear environmental risk assessment (ibid.). This is particularly important because hereby, Greenpeace turns the argumentation around, leaving the impression that EFSA lacks scientific expertise in its argumentation and reports. At the same time, Greenpeace admits that their own scientific analysis cannot be seen as the only correct risk assessment either, but rather as another scientific analysis in this context (ibid.). Hereby, Greenpeace acknowledges the existence of scientific uncertainty in the framework of GM-crops, without explicitly stating it.

The following statement further il ustrates Greenpeace's awareness of scientific uncertainty:

> "How can EFSA come up with a positive opinion on MON810 when it has publicly recognised its inability to determine the long term impacts of GM crops? Allowing EFSA to express opinions on GM crops while it cannot assess long term environmental impacts is like allowing someone into a Formula 1 race just because they have a driving licence," (Greenpeace, 2009b).

Indeed, in all six analysed publications, Greenpeace frequently refers to scientific uncertainty. We identified a total of seventeen references to the concept within which Greenpeace specifically links scientific uncertainty to the lack of valid data provided by EFSA as is exemplified by the statement above. Hereby it is striking that the acknowledgment of uncertainty is present throughout all the various publications. Thus, unlike scientific references which are more explicit in publications focusing on a specific GMO, uncertainty is mentioned throughout all the publications to a similar extent.

Other findings reveal that over time, Greenpeace seems to have changed its deployed string of argumentation. On the one hand, the scientific argumentation seems to have changed focus. While specific GMOs were criticised in the beginning, attention has increasingly shifted to GM-maize in general; without specifically criticising the European risk assessors or managers and their research regarding the environmental effects of GM crops (Greenpeace 2009; 2011). On the other hand, the addressee of Greenpeace's critique has changed. While earlier publications focused mainly on EFSA (the risk assessor), Greenpeace over time turns to criticise EU policy makers (risk manager) for authorising the cultivation of GM-crops as it allegedly enhances environmental threats (Greenpeace, 2009a).

Furthermore, the structural as well as the analytical developments of the publications generate the impression that Greenpeace focuses increasingly on scientific evidence and scientific reasoning within their argumentation. This might be due to tactical considerations, of using the 'same weapons' as risk assessors and risk managers, moving the argumentation on one (scientific) level. Thereby, discussion might be simplified on two levels. On one side, risk assessors and managers might turn to see NGOs as a more credible partner; thus, easing the way for more political influence of NGOs. At the same time, the discussion becomes better to grasp for society as different arguments are based on the same sources - simplifying Greenpeace's task to convince society about their findings.

3.2 Friends of the Earth Europe

> *"In Europe, the authorisation process for genetically modified (GM) crops is based on the assessment of risks for health and the environment. Evidence [...], however, shows that the cultivation and trade of GM crops has far-reaching impacts which are not covered by the EU's legal framework for genetically modified organisms." – FoEE, 2010*

Friends of the Earth (FoE) is an international NGO concerned with the promotion of a sustainable environment. The European branch (FoEE) seeks to improve public participation in European environmental and social policy making. In total, the analysis covers thirteen publications by FoEE on the topic of GMOs, out of which ten specifically deal with MON810. Even though there is no report, which exclusively discusses Bt-11, it is frequently referred to in the other reports. The publications that specifically cover MON810 comprise two media briefings (FoEE, 2006a; FoEE, 2006b), two comments from the public[6] (European Commission, 2006; European Commission, 2009), and five web page articles. Furthermore, there is one extensive report that criticises EFSA's opinion on MON810, which was conducted in cooperation with Greenpeace (Greenpeace, FoEE, 2009), and has been covered in the prior section.

Illustrating the variety of FoEE's work, the analysis comprises publications, which have been drawn up for different purposes, areas and settings. As the range of chosen publications has been so broadly defined, our analysis is by far not extensive but rather offers examples and first indications towards possible answers of our research question. The choice of publications was further limited by our premise to only use documents written by FoEE, thereby disregarding publications by Friends of the Earth International, or of national sections of FoEE.

Within the ten specific publications on MON810, we identified twenty-nine references to scientific knowledge, of which we rated fifteen to give explicit reference to the origin of the scientific knowledge. Classified to give either no references or general references were seven statements of scientific knowledge respectively (see Appendix, Graph 2). That

6 Comments of the public are part of the public consultations within the authorization process of GM food and feed, regulated by Regulation 1829/2003. The consultation of the public takes place after EFSA has published its risk assessment and before a GMO can be approved.

means that approximately half of all scientific claims have indeed been backed up by explicit references close to the academic style. The common claim prevalent especially among policy makers and expert advisers that NGOs' claims or opinions are often not based on scientific research (Wynne, 1996; Lynas, 2013), does therefore not hold per se.

Interestingly, one can observe a correlation between the use of scientific references and the type of publication. The web page articles of FoEE generally use less scientific claims. Of the five web page articles only one did not use any scientific claims (FoEE, 2009a), one article included three scientific claims (FoEE, 2009b), and the other three each used only one scientific claim (FoEE, 2008; FoEE, 2009c; FoEE, 2012). Of these six scientific claims, only two were supported by explicit references, whereas two were not backed by any references at all. Among the other publications (report, media briefing and comments from public), the scientific references are quite evenly distributed with a tendency towards a majority of explicit references. Only one media briefing does not contain any explicit references (FoEE, 2006a).

A possible explanation to why web page articles do not contain as many scientific claims in general could be that they often refer back to reports, which are more detailed and which, as shown above, do refer back to scientific evidence. As the web page and its articles are of course the most accessible information given by FoEE its content needs to be suitable for people with very diverse backgrounds. On the other hand, a tendency for too much simplicity on the web page could explain why NGOs are perceived to focus on non-scientific argumentation or to predominantly involve in an ethical discussion about GMOs.

When looking at the references used in the reports, it becomes evident that the claim that NGOs are non-scientific, again does not hold per se. It is striking that *all* scientific studies FoEE quoted as reference to a scientific claim, were based on peer-reviewed research; a fact which makes FoEE more credible as they themselves criticise EFSA harshly for basing their risk assessment not exclusively on peer-reviewed studies (Greenpeace, FoEE, 2009). Furthermore, FoEE appears to be quite cautious in the usage of scientific knowledge. This is illustrated by the fact that FoEE repeatedly points to the scientific uncertainty surrounding the knowledge on GMOs; another issue EFSA has been criticised for not doing (European Commission, 2009, p.5). For example, regarding GMOs to potentially cause allergies FoEE states: "There is currently no validated [...] model for al ergenicity testing, so clearly further research is needed. [Therefore], it seems premature to conclude a low probability of al ergenicity." (European Commission, 2006, p.12). Within the ten publications discussing MON810, FoEE elaborately hinted to scientific uncertainty twelve times, using it as an argument against the cultivation of GMOs.

Apart from case-specific analyses, FoEE also publishes about GMOs in general. However, most of these publications have been written by Friends of the Earth International. This indicates that, by focusing on particular GMO variants such as MON810, the European branch of FoE has adopted the working style of the European Union with regard to GMOs: namely the case-by-case analysis. This hypothesis can be further strengthened when taking a closer look at the few publications covering GMOs in general, which have been written by FoEE. Since 2007, the general reports and analyses by FoEE do not so much cover the safety of GMOs, but rather concentrate on the economic implications of growing GMOs (FoEE, 2007; FoEE, 2010). Therefore, during the years of economic crisis, the argumentation of FoEE has shifted from concern about hazard for health and environment, towards an economic reasoning of GMOs not being profitable. The scientific evidence used, is thus less derived from studies conducted by natural scientists, but increasingly by economists stemming from the social sciences.

By doing so, FoEE's strategy vis-à-vis GMOs is moving on a two-edged sword. On the one hand, the argumentation based on economic evidence matches the social circumstances Europe is currently facing. On the other hand, FoEE has harshly criticised the European Commission for focusing too much on economic growth and competitiveness in the biotechnology sector (FoEE, 2007), rather than on the underlying question of whether Europe and its citizens want to involve in the growing of GMOs. By widely neglecting the ethical discussion in its economic analyses, FoEE follows the European Commission in deferring the fundamental argumentation on ethics and European values - at least for the moment.

3.3 Specialised NGOs

> *"The controversial debate on GM foods has clearly demonstrated that public concern cannot be resolved by science alone. Many other factors, including social values, attitudes and beliefs, will also impact on consumer acceptance. We believe that it is important that these factors are reflected in the risk management decisions" (BEUC, 2001, p. 2)*

The analysis of this section contains publications by the FOAM EU Group, the BEUC, CEO, Euro Coop, and ECVC. These NGOs boast quite different backgrounds and various fields of activity: IFOAM EU group and ECVC broadly focus on the promotion of organic agriculture

and address the controversial issue of seed contamination from GM-crops throughout Europe, whilst BEUC and Euro Coop claim to represent the interests of European consumers. Lastly, CEO aims to scrutinise corporate lobbying on the EU level.

As Greenpeace, FoE and indeed most NGOs concerned with environmental issues, most of the analysed specialised NGOs generally oppose the development and cultivation of GM-crops, the distribution of genetically-modified foodstuffs and genetic engineering in general. The grand exception to that is BEUC, which does not condemn GMOs outright but instead promotes transparent information about GM-products to guarantee the freedom of choice for consumers. Of the five NGOs, this section analyses seventeen publications, comprising three open letters, two web page articles, three position papers, one position statement, one policy position, three press releases, as well as three BEUC - publications commenting on documents issued by European risk assessors and risk managers.

Regarding the content of the publications, it appears that specialised NGOs engage less frequently in case-specific in-depth analysis of a single GMO than Greenpeace or FoEE. We have identified only four publications that mention MON810 and/or Bt-11, whereby the focus nevertheless remains on a general debate about GMOs (IFOAM, 2009; IFOAM 2010a; ECVC, 2012; CEO, 2009). The two specific GMOs are rarely addressed, or in any case, never referred to as detailed as Greenpeace and FoEE do this. This stands in stark contrast to the number of generally available publications on the web pages of all six NGOs as well as to the degree of coverage that we have observed with regard to Greenpeace and FoEE. Indeed, in particular IFOAM EU Group publishes extensively on GMOs and the seed contamination controversy, however, mostly without referring to specific GMOs such as MON810 and Bt-11.

Particular reasons explaining why these NGOs engage less in case-specific examinations of GMOs can be found with regard to their organisation and working-practices. As each of the covered NGOs work within a thematic framework such as consumer rights or organic agriculture, GMOs are often only placed within the wider context of the specific field of expertise. For example, Euro Coop (2010) covers the topic of the Common Agricultural Policy (CAP) in a position paper, within which they state the use of GMOs as just one aspect among many in order to underline the importance of a consumer-friendly CAP. IFOAM EU Group, for instance, addresses both MON810 and Bt-11 in its publications to substantiate claims on the alleged contamination of conventional crops by GMO crops, thereby referring to the issue of the "coexistence of genetically modified crops with conventional and organic farming" (IFOAM EU Group, 2010a, p.1). This clearly refers back to IFOAM EU Group's strive for the promotion of organic agriculture throughout Europe. Thus, it emerges that in case specialised NGOs refer to specific GMOs

such as MON810, they often do so in the context of another topic, mostly related to their particular organisational identity.

On the basis of these findings, we can assume that the fact that these NGOs operate according to one specific thematic field and objective, influences the way scientific knowledge is used. It seems that it is not the priority to convince the public and policy makers of the general danger of GMOs. Rather this claim is embedded into the thematic area of the respective specialised NGO, for instance by underlining the threat that GMOs entail in regard to organic agriculture (ECVC, 2010b). Thus, it is assumable that the scientific knowledge used is adjusted towards the specific area of expertise.

Further, the analysis shows that the scientific sources that are employed by the five NGOs are not limited to natural sciences alone, but also include references to social sciences (IFOAM EU Group, 2011; IFOAM Group, 2010b). For example, ECVC (2010a) refers to a study, which outlines the socio- economic impacts of GM-crop cultivation on organic farming in Spain. BEUC, which has a special focus on GM-labelling, uses a number of studies (i.e. by the Food Safety Authority of Ireland), showing that many products labelled as GM-free do in fact contain traces of GMOs (BEUC, 2002). In another report BEUC (2004) explicitly states: "We would appreciate [the] recognition of possible ethical concerns" (p. 3).

This indicates that specialised NGOs base their line of argumentation within the wider ethical or socio-economic discussion. Thus, the usage and the sources of scientific knowledge differ between NGOs and public authorities, which focus on natural sciences and often come short on considering ethical concern. One could assume that NGOs tend to use social sciences as it provides evidence that fits the specific field of expertise of a given NGO. As NGOs participate mainly in an ethical or socio- economic discussion it follows that their argumentation cannot be based solely on natural scientific evidence.

This interpretation of our findings might also explain why references to natural scientific sources appear to be used rather sporadically throughout the specialised NGO's publications. Indeed, within the seventeen analysed publications, only five scientific claims were backed by explicit references to scientific studies (CEO, 2009; BEUC, 2004; IFOAM, 2010a). Thus, while specialised NGOs do use scientific knowledge to back up their claims – at least to a certain extent – they only refer to explicit scientific sources in very limited manner. In this respect, our findings can only partially confirm Yearly's claim that NGOs increasingly aim to substantiate their positions using "scientific warrant(s)" (1996, p. 173).

Indeed, two of the NGOs (Euro Coop and ECVC) do not invoke any explicit scientific references. Moreover, out of all five NGOs a total of nineteen scientific claims do not provide any references at all (see Graph 3). IFOAM EU Group, for instance, refers in one of its position papers to the "unprecedented danger [...] and the particular economic and

environmental risks" (IFOAM EU Group, 2009) GMOs entail, without scientifically backing this claim. Additionally, ECVC issues four scientific statements on GMOs in its two web page articles and one position statement but it does not refer to any type of reference. For example, ECVC (2010a) stresses that "an increasing number of scientific studies prove that GMOs are harmful to health and the environment and that, by contaminating other crops, they endanger biodiversity". This is striking, as the NGO mentions scientific studies but does not indicate the origin or content of these studies. Similarly, Euro Coop uses scientific claims without any reference (Euro Coop, 2010). The same strategy can be observed with regard to BEUC (eight times) and CEO (four times), which also issue claims on the perceived dangers of GMOs without any scientific basis.

It becomes apparent that all of the specialised NGOs have a tendency to present scientific claims without reference to natural scientific sources. As a consequence, it is difficult to assess how they gain natural scientific knowledge and on what type of scientific evidence they base their claims. It is striking though that the specialised NGOs tend to refer back to publications written by other NGOs such as Greenpeace or FoE. For instance, IFOAM EU Group drew up two publications that include references to scientific sources and/or studies by other NGOs, such as Greenpeace (IFOAM EU Group, 2010a; IFOAM Group 2010b). In addition, CEO (2009) in its open letter refers back to a statement by FoE. Equally, this tendency can be observed for ECVC, which provided a reference to a study, which has been pursued by five other NGOs, including Greenpeace and FoE (ECVC, 2010a). A possible explanation why the specialised NGOs tend to regularly use sources provided by NGOs such as Greenpeace or FoE might be that the latter are much better equipped to conduct academic research, or even produce scientific knowledge themselves (see Greenpeace Science Unit).

Following this analysis, we come to two conclusions about how specialised NGOs use scientific knowledge. First, the usage of scientific knowledge might not be apparent to the reader of these publications at first sight. Since publications such as web page articles or press releases are mostly intended to be read by the public, NGOs might seek to deliver a general overview of their specific topic without overwhelming the reader with too complex scientific information and references. Thus, it appears that specialised NGOs provide 'uncomplicated' and easily accessible information by consciously compromising on sound scientific sources. However, this choice fosters the impression, generally represented by natural scientists, that NGOs are non-scientific (Wynne, 1996).

Second, it appears that specialised NGOs do extensively refer to scientific uncertainty instead of scientific knowledge. To foster their argumentation, these NGOs seem to focus on scientific uncertainty, thereby often pointing to the need of further research on GMOs.

A possible explanation for this strategy is that NGOs generally tend to equal uncertainty with risks. In this regard, Van Asselt and Vos (2008) argue: "Risk protesters highlight uncertainty to demonstrate risk" (p. 291), which is in line with our finding. Indeed, within the seventeen analysed publications, we found a total of twelve references to scientific uncertainty.

To give an example, Euro Coop in all three of the analysed publications refers to scientific uncertainty, stressing the need to "investigate the mid-and long-term effects that the use of GMOs could have on human health and the environment" (Euro Coop, 2008a; Euro Coop 2008b; Euro Coop, 2010). In contrast, it never uses detailed scientific evidence to either back up its general arguments or its emphasis on scientific uncertainty. Moreover, specialised NGOs tend to refer to uncertainty not solely with a pure focus on natural science but often consider the phenomenon in a wider socio-economic context (Euro Coop, 2008a; Euro Coop 2008b; Euro Coop, 2010). ECVC (2010a), for example, points out: "Socioeconomic impacts give a first impression of the potential difficulties GMOs can cause in Europe, the long-term effects of which are difficult to quantify".

4. Rounding It Up: How NGOs Use and Gain Scientific Knowledge

Following the case analyses, several observations are worth to cover on a more general level again as they seemed to reoccur throughout the analysed NGOs. These general tendencies are all the more relevant because every NGO differs from the others in regard of working practices, ideology, or resources at hand. Being able to identify patterns of how these different NGOs gain and use scientific knowledge, might give a first indication of how NGOs in general use scientific knowledge. Thus, this section of the paper attempts to map the variety of NGOs working in the field of GM-regulation while at the same time trying to make some first generalisations of how scientific knowledge is gained and used by NGOs.

First of all, one can categorise NGOs according to two general types. Some seem to act very openly, trying to actively influence the regulatory system by campaigning against GMOs. Most visible in doing so are Greenpeace and FoE, often also cooperating with each other. In general, these two NGOs manage to regularly gain a high degree of attention from the public and the media (Yearly, 1996). In contrast, other NGOs' work is less publicly visible. Indeed, IFOAM EU Group, Euro Coop and others are less well known. One can only speculate on the reasons. It might be that specialised NGOs do not have the necessary

resources for a catching and effective media campaign or for drawing up thorough reports. This could explain why some of the specialised NGOs repeatedly refer back to Greenpeace or FoE, accessing their more extensive resources. Another explanation could be that some NGOs wilfully stay out of the spotlight because without the time-consuming media and publicity work, more content work can be conducted and subsequently promoted via the channels of Greenpeace or FoE.

A second observation hints at the different approaches of how GMOs are addressed by NGOs. On the one hand, there is an engagement in the general discussion surrounding the desirability of GMOs, posing questions of ethics and values. On the other hand there are very specific reports by NGOs discussing one GMO in particular. It seems that the NGOs closest to influencing the regulatory process – namely Greenpeace and FoEE – tend to engage in a case-by-case analysis of GMOs, apparently adapting to the European regulatory system of GMO-authorisation. This approach might enhance the possibilities of NGOs to influence European decision-making as it offers the possibility to be regarded as professional partners fulfilling their assigned roles as indispensable actors in risk assessment. Contrasting, the wilful assimilation to the working practices of a regulatory system designed by state authorities could raise doubts on the impartiality of NGOs and their approach to GMOs. This might endanger their traditional role as a watchdog in policy-making on behalf of civil society (Bieri, 2010).

Nevertheless, one must recognise that NGOs do not fully adapt to the working style of the official institutions but maintain their distinct characteristics as risk protesters. For example, within the case-specific reports by NGOs that are predominantly based on natural scientific knowledge, the ethical dimension of the usage of GMOs is mostly included – a point that EFSA and the European Commission have been accused of failing to include. Thus, NGOs do not limit themselves to a natural scientific argumentation. Rather, NGOs gain scientific knowledge from an interdisciplinary background, combining natural and social sciences (Jamison, 1996). Thereby, it could be argued that NGOs aim to enrich their line of argumentation by employing a diversified argumentative structure, making themselves relevant to multiple disciplines.

However, our third observation poses some limits to the role of ethics as a major distinction between NGOs and the public actors. It seems that there is a shift within the social scientific string of argumentation; turning from the ethical- or values-argument towards currently salient issues. For example, one could observe that during the economic crisis NGOs make use of financial arguments against GMOs (FoEE, 2010), whereas traditionally ethical concerns or health issues prevailed as argumentation contra GMOs. Thus, even though NGOs do not base their argumentation exclusively on natural sciences

but also utilise social science for their argumentation, this is no guarantee for engaging in the general ethical discussion.

This leads us to a closely related fourth observation concerning the sources NGOs' argumentation is based upon. Following our case analyses, we argue that NGOs increasingly use scientific argumentations (from natural and social sciences alike), adopting an academic working style. One indicator is the frequent usage of explicit reference to scientific knowledge, as only twenty-five per cent of all scientific claims within the thirty-six analysed publications did not entail references (see Graph 4). Another indicator backing this claim is the fact that NGOs measure their work and the work of others on academic standards. For example they repeatedly engage in a discussion on the quality of the academic and scientific sources used. For instance, EFSA is criticised for not basing their opinion on peer-reviewed studies (Greenpeace, FoEE, 2009). Likewise, NGOs underline that they themselves aim to exclusively refer back to studies, which have been peer-reviewed. Hereby, NGOs are often dependent on studies conducted by scientists or academics. Greenpeace's Science Unit poses the only exception in providing internal natural scientific research. Nevertheless, its influence must not be overrated as resources are limited and only a certain number of studies can be conducted by the Science Unit. Thus, NGOs in general are usually dependent on academic output by natural and social scientists, which limits their argumentation to findings of external sources and might again obstruct their impartiality.

However, at the same time, by not conducting scientific research NGOs could be somewhat more objective in their usage of science as they can independently select from a pool of scientific knowledge. Yearly (1996) strengthens that argumentation in claiming that NGOs, such as Greenpeace and FoE, are able to be more critical of science and expert opinion, as they themselves do not have a "scientific ancestry"[7] (p. 181). Our analysis confirms that claim, as especially EFSA's scientific opinion on GMOs are quite heavily criticised by Greenpeace and FoEE. In doing so, NGOs often tend to use similar scientific sources as EFSA (e.g. Greenpeace, FoEE, 2009). Showing that one study could be interpreted in quite opposing ways, NGOs reflect on EFSA's reading and interpretation. Thus, one could depict NGOs as 'peer-reviewers' of EFSA's use of science.

Nevertheless, NGOs ultimately remain lobby organisations representing only one group of interests, supported by a deliberate selection of scientific knowledge. It should not be disregarded that the 'selective' approach of NGOs vis-à-vis science as employed

7 As opposed to established scientific conservation bodies, for instance the Royal Society for Nature Conservation.

in their argumentative structure can potentially be highly problematic. If addressing issues one-sidedly by exclusively using science that fits their respective claims, NGOs may partially avail themselves with the common prejudice of their work being ostensibly 'un-scientific'. It is, thus, necessary to critically scrutinise the role of NGOs in the policy-making process and not blindly accept their alleged role of being the undisputed moral authority.

Hereby, it is interesting to observe that NGOs are well aware of their assumed role as moral authority representing civil society (Bieri, 2010; Piattoni, 2010). Nevertheless, they do not claim to have a monopoly on 'the truth'. Instead they revert to the concept of uncertainty to support their claims. Indeed, our fifth observation indicates that NGOs – despite their variety – explicitly refer to scientific uncertainty. We repeatedly found references to uncertainty in all the analysed publications. This could on the one hand indicate that NGOs tend to deal with uncertainty more responsibly than the European risk assessor EFSA, which has been criticised to deliver certainty statements in uncertain situations (van Asselt & Vos, 2008). It appears that NGOs do not use scientific knowledge to claim that GMOs are generally unsafe and dangerous. Rather, opposing scientific evidence is used to illustrate uncertainty, showing that there can be no absolute argument made in favour of the safety of GMOs. Hereby, our findings confirm the claim that NGOs equate uncertainty with risk (ibid.).

On the other hand, the frequent reference to uncertainty could result from the lack of supporting scientific evidence (as NGOs are dependent on research conducted by others), which is compensated by "creat[ing] sufficient uncertainty to delay political action" (Brown, 2009, p. 12). As van Asselt (2005) suggests, there are two major modes why uncertainty is acknowledged: first, "to create the *sense of uncertainty"* (p. 143), and second, to establish *uncertainty information* – hinting at the importance of recognising uncertainty as a first step for actually reducing it. This is usually done by pointing out that more studies and information are necessary to address the issue of uncertainty.

Having outlined the five main observations from our analysis, the use of scientific knowledge by NGOs could widely be characterised by a general dependency on gaining scientific knowledge from existing literature and research. Out of the perceived need to be seen as more credible partners by policy makers, officially associated experts and the public, NGOs have adapted to their intended audiences.

We argue that NGOs hereby attempt to incorporate two distinct interests within their argumentation, which makes it difficult to adopt one coherent position. On the one hand, the wish to be perceived as credible actors by public authorities and official experts within the risk regulation process leads NGOs to increasingly adopt a natural scientific string of argumentation. Employing this more 'sober', 'scientific' and less emotional approach, NGOs

refute claims of an al eged "anti-science" (Lynas, 2013) but lose sight of public concerns. On the other hand, it is essential that NGOs fulfil their role as a reliable representative of public concerns because their entire *raison d'être* and legitimacy is derived from that role. However, by deviating too much from the official framework, NGOs' involvement in the policy making process might become undermined as they are not seen as professional partners. By trying to be seen as relevant partners on all levels at the same time, NGOs risk to lose sight of their original role as ethical defender.

Our analysis confirms this dilemma hinting at two tendencies within the development of NGOs' argumentation. One concerns the social scientific argumentation, the other the natural scientific: First, NGOs have shifted towards an economic reasoning because socio-economic concerns have become omnipresent and salient to society. Consequently, ethical considerations have lost their dominance within the social scientific string of argumentation. Second, NGOs have adapted to the European policy- making process. Hereby, the focus has increasingly turned to a natural scientific argumentation, adopting the case-by-case analysis of the European authorisation process. As the authorisation of a single GMO is based on the scientific opinion by EFSA NGOs counter-argumentation makes use of the same methods; providing contrasting natural scientific evidence.

Thus, the extensive use of natural sciences in connection with the shift of argumentation within the social sciences could pose another problem to NGOs. By deviating from their traditional role, NGOs might become 'just another' actor within the policy-making process; thereby, tending to compromise their traditionally assumed ethical and moral leadership role, and potentially even running the risk of losing it. The question arises whether NGOs will manage to be taken as credible partners by all parties while at the same time fulfilling their role as ethical defenders. If NGOs were to lose the ethical leadership role, a significant gap would arise, leaving the ethical aspects without proponents. To avoid this, it seems that there is a need for enhanced collaboration and division of labour between the various NGOs to ensure that the ethical discussion does not get out of focus.

5. Conclusion

As this paper has shown, the complexity of science-based policy-making is particularly visible with regard to GMO risk regulation. Despite a generally positive notion towards scientific progress, genetic engineering remains one of the most disputed scientific developments of modern times. In today's modern European society, widespread public

concern on the safety of GMOs is essentially channelled, reflected and reinforced by NGOs. On the one hand, the relatively high trust NGOs enjoy among civil society, potentially renders them one of the most powerful stakeholders in the process of risk regulation and policy-making. On the other hand, being recognized as a legitimate actor on behalf of civil society increasingly puts NGOs under pressure to 'professionalize' by yielding to their audience in an increasingly scientific way, thereby conforming to the science-based policy-making on the European level, where decision-making on GMOs is essentially based EFSA's opinion.

In this context, this paper constitutes an attempt to shed light on the way NGOs use and gain scientific knowledge; thus filling a gap in the literature that assesses the influence of NGOs on policy making on the one hand, and the influence of science on policy making on the other. In this context, our findings suggest that the claim that NGOs are unscientific cannot be substantiated. As shown in our analysis, NGOs frequently use scientific knowledge within their argumentation, and adhere to high academic standards (such as using peer-reviewed articles). This is particularly the case when a specific GMO is discussed within a publication, adopting the case-by-case style of the European authorisation process.

If no – or only contrasting – scientific evidence can be provided NGOs seem to be willing to provide reference to scientific uncertainty. However, we can only hypothesize if this is a result of them acting more responsibly by acknowledging the fact that there simply is no ultimate scientific certainty, or whether NGOs use scientific uncertainty as a tool to stall the policy-making procedure by equating scientific uncertainty with risk. It can thus be concluded that NGOs use science in a sensible way and have a keen interest in engaging in a discussion with the European regulators in the same language – that of expertise and science.

However this tendency poses a problem to the identity of NGOs. By succumbing to the pressure to 'professionalize', conforming to the high natural scientific standards of policy-making on the European level, NGOs become recognised as credible actors in the field. At the same time, when moving closer to the EU's bureaucratic practices, NGOs run the risk to lose their connection to civil society. Traditionally, the relationship between NGOs and civil society is characterised by a relatively high trust and an acceptance of NGOs as representatives of marginalised groups. Nevertheless, we can only hypothesize in what way this 'professionalization', in terms of an enhanced focus on (natural) sciences, could put the traditional ethical and moral *Leitbild* of NGOs at risk.

In consequence, our findings have raised further questions, which however extend beyond the scope of this paper. Nevertheless, we consider it of importance and interesting

broader significance to mention these questions, which shall guide further research in this area. As NGOs increasingly shun their traditional role of heralding ethical points of discussion, who is going to fill this gap? And, if NGOs at the same time remain critical of the usage of science, how can they solve the paradox of being critical of science whilst at the same time making use of it? Can this paradox increase the tendency of different stakeholders to interpret similar facts in different manners, cherry-picking what they regard as 'right' science over 'wrong' science?

This increasingly instrumental approach to science might lead to new ways in which policy makers could use science in the future. Another scenario could be that instead of using science as the only possible and credible guideline, science might be increasingly advanced as a tool, for example to back up claims, which are grounded in ethics. Out of this a paradigm shift might evolve, which changes the role of science in so far that the inability of science to deliver certainty or the absolute truth is accepted.

For this reason, we strongly encourage future research in the field, especially with regard to questions of philosophy and ethics, (e.g. who takes over the ethical role of NGOs and if they do it themselves, how can they allow science and ethics to peacefully co-exist in a single argumentation?), political sciences (how do NGOs use social sciences?) and risk research to craft an overarching theoretical framework on the use of scientific knowledge by NGOs. Whilst this paper has not attempted to create such a framework, it has mapped and organised the existing variety, thereby establishing a starting point for further research in this field.

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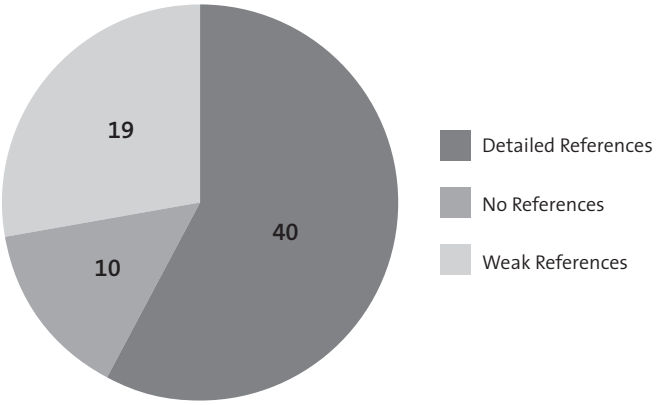
Appendix

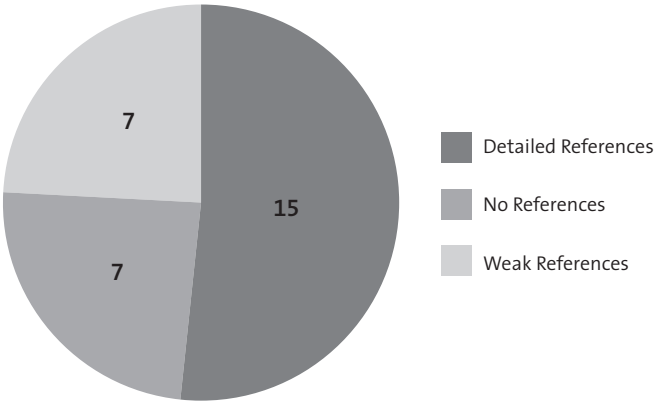
Graph 1:

Scientific References of Greenpeace, in six reports on MON810 and Bt-11



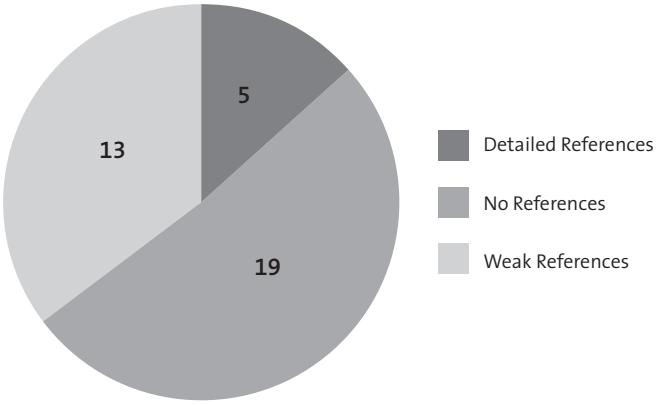
Graph 2:

Scientific References by FoEE, in publications specifically discussing MON810 (10 reports)



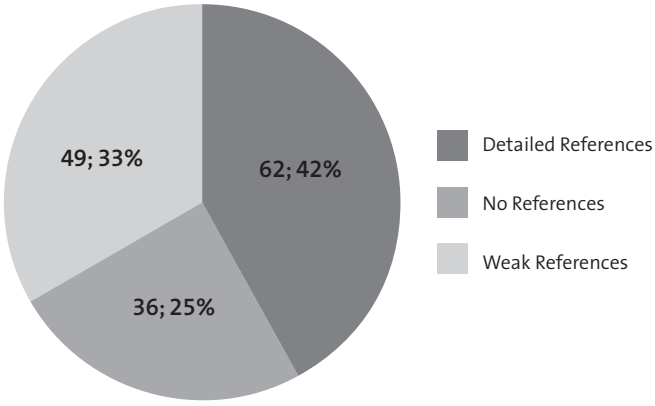
Graph 3:

Scientific references by specialised NGOs (17 Reports)



Graph 4:

Scientific Refereneces by NGOs in reports about GMOs (36 reports)



Unlocking the Deadlocks?

GMOs, Science and the Reform of the Legal Framework

Inka Eberhardt, Daniel Limberg, Dorottya Liptai, Nele Rosenstock, Lucas Unterberg, Trebor Wagner

Table of Contents

1. Introduction

> Hydra |ˈhīdrə|- *"In Greek mythology, a many-headed snake whose heads grew again as they were cut off, ... in figurative usage, a thing which is hard to overcome [or resist because of its pervasive or enduring quality] or its many aspects".*[1]

The hydra is in many ways a well-working allegory for the numerous conflicts the EU has been facing in the GMO authorization process, and in particular regarding the complex deadlocks in the authorization of GMOs for cultivation. In the 1990s, heavy pressure at the international level[2] caused the responsible EU decision-makers to establish a regulatory framework[3] and the European Food Safety Authority (EFSA)[4] to finally resolve their struggles with the *de facto* moratorium on GMO authorization. Unfortunately, this solution to the conflicts and struggles with GMO authorization did not prove to be sufficient. Even worse, the EU decision-makers faced what we call the first deadlock. It originated from the continuous bans of GMOs that Member States imposed with the safeguard clause,[5] now in particular on GMO cultivation.[6] As with the Hydra's many heads which are growing back numerously every time one head is cut off, each time one issue was solved in the GMO authorization process, numerous other problems came up.

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1 Oxford University Press: Hydra; retrieved on 13/06/2013: http://www.oxfordreference.com/view/10.1093/oi/authority.20111017150154589?rskey=3KCgXF&result=8&q= hydra.

2 For more information see: Caroline Henckels, "GMOs in the WTO: A Critique of the Panel' Reasoning in the EC – Biotech", 7, *Melbourne Journal of International Law* (2009), pp. 279 et *sqq*; Jacqueline Peel, Rebecca Nelson and Lee Godden, "GMO Trade Wars: The Submissions in the *EC – GMO* Dispute in the WTO", 6, *Melbourne Journal of International Law* (2005), pp.141 et *sqq*.; Antonia Eliason, "Science versus Law in WTO Jurisprudence: The (Mis)interpretation of the Scientific Process and the (In)sufficiency of Scientific Evidence in *EC-Biotech*", 41, *International Law and Politics* (2009), 41, pp.341-406; David Winickoff, Sheila Jasanoff, Lawrence Busch et al., "Adjudicating the GM Food Wars: Science, Risk, and Democracy in World Trade Law", 30, *The Yale Journal of International Law* (2005), pp.82 et *sqq*.

3 European Parliament and Council Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, OJ 2001 L 106.

4 European Parliament and Council Regulation (EC) No 178/2002 on the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 031, 1.2.2002, p.1.

5 Directive 2001/18/EC, *supra* note 3, Art. 23.

6 Austria, France, Greece, Hungary, Germany and Luxembourg, from: DG Health and Consumers, "Rules on GMOs in the EU – Ban on GMO cultivation", no date, available on the Internet at http://ec.europa.eu/food/food/biotechnology/gmo_ban_cultivation_en.htm (last accessed on 14 June 2013).

When over time the new directive and agency proved not be the solution to the many conflicts and as there was no sign that GMO-opposing Member States would finally stop the banning, Member States from both camps – anti- and pro-GMO – instrumentalised the Commission[7] to end the conflict on GMO authorization. The Commission attempted to do so by drafting a proposal,[8] which arguably gave the Member States more freedom in deciding whether or not to cultivate GMOs in their territory.[9] Thereby the Commission expected to accelerate the general authorization procedure for GMOs, as anti- GMO Member States could on the one hand agree on authorization of GMOs at the EU level, but also had the opportunity to ban their cultivation on national territory. Irrespective of the Commission's attempt to solve the conflict and give the Member States more freedom, the proposal did not succeed in solving the deadlock. It was heatedly debated by EU officials and stakeholders,[10] partly amended by the European Parliament (EP)[11] and has not been adopted yet, as a blocking minority in the Council exists. We label this

7 Council of the European Union, "Genetically Modified Organisms – A Way Forward"; 23 June 2009, available on the Internet at: http://register.consilium.europa.eu/pdf/en/09/st11/st11226-re01.en09.pdf (last accessed on 14 June 2013). Note submitted by the Austrian delegation, supported by Bulgaria, Ireland, Greece, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland and Slovenia. Also referring to the Netherlands: "The Netherlands delegation came up with a declaration et the last Environment Council on 2 March 2009 calling for Member States to have the right to decide for themselves on the cultivation of GMOs. The delegations cited above appreciate this initiative and are willing to develop et further in order to find a satisfactory long-term solution" (p.2). "On June 24, 2009 a number of Member States (namely Austria, Bulgaria, Ireland, Greece, Cyprus, Latvia, Lithuania, Luxembourg, Hungary, Malta, the Netherlands, Poland and Slovenia) requested that the Commission give Member States the freedom to cultivate plants based on "relevant socio-economic aspects". On July 13, 2010 the EU Commission announced a proposal for the addition of one article to Directive 2001/18/EC, which would explicitly allow Member States to restrict or prohibit cultivation of GMOs on their territories" Shane H. Morris & Charles Spillane, "EU GMO Crop Regulation: A Road to Resolution or a Regulatory Roundabout?", 4, *European Journal of Risk Regulation* (2010), pp.359 et *sqq*., et p.365.

8 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) 380 final, COM(2010) 4822 final.

9 EurActiv, "EU wants to put GMO dispute to an end", 5 November 2010, available on the Internet at http://www.euractiv.com/cap/eu-wants-put-gmo-dispute-news-496059 (last accessed on 13 June 2013); EurActiv, "EU move to break GM deadlock could sow discord", 5 November 2012, available on the Internet at http://www.euractiv.com/cap/eu-move-break-gm-deadlock-sow-di-news-495753 (last accessed on 13 June 2013).

10 EurActiv, "EU GMO proposals draw widespread criticism", 5 November 2012, available on the Internet at http://www.euractiv.com/cap/eu-gmo-proposals-draw-widespread-news-496263 (last accessed on 13 June 2013).

11 Corrine Lepage, *Report on the 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)0375 – C/-0178/2010 – 2010/0208(COD))*, Report issued by European Parliament on 20 April 2011.

situation the 'second deadlock' – namely the deadlock on the solution of the first deadlock. After a couple of years of silence on this situation, the proposal and the whole deadlock situation suddenly became news again, when the Commission announced the revival of the talks[12] and Monsanto, one the biggest GM producing companies, threatened to leave the European market in 2013.[13]

GMO authorization in the EU was never an easy topic, partly because the European public is not very fond of the idea of having GM-food on their table.[14] Therefore, not only the heads of the hydra, but also the hydra itself can be compared to the GMO authorization process. In Greece mythology, the hydra was hated by the public as it murdered the farmers' cattle at night. Unfortunately, up to now there was no Herakles in the EU, being able to find a solution on how to solve the deadlocks in GM- authorization. As there is no complete solution evident at the moment, we investigate to what extent the two deadlocks might be unlocked, also in light of the high prevalence of the topic in the news. Even though we are aware of the manifold aspects surrounding GM-authorization and cultivation, we aim to provide an overview for a broad scholarly public, not only on how the two deadlock arose and what were the exact issues at stake but also regarding the many heads of the hydra – namely the many issues decision-makers need to take into account – when trying to unlock the deadlocks. After explaining our research approach and methodology, our analysis first provides a general overview on the regulatory framework on GMOs. By describing the problems of authorization in practice, we investigate the first deadlock. Subsequently, some of the Hydra's heads are cut off by means of analysing whether or not science is the solution to the first deadlock. The fourth section presents the Commission's proposal to solve the deadlock, which is subsequently analysed on its legal viability regarding EU and WTO legislation. It is then attempted to solve the deadlock, or at least to provide some ideas on how to move a step towards solving it. Before concluding, we embed our proposal in the latest state-of-the-art academic literature.

12 Reuters, "EU seeks to revive talks on GMO crop cultivation", 22 January 2013, available on the Internet at http://uk.reuters.com/article/2013/01/22/eu-gmo-cultivation-idUKL6N0ARCX620130122 (last accessed on 6 June 2013).

13 EurActiv, "Disgruntled GMO firms start pulling et of EU market", 25 January 2012, available on the Internet at http://www.euractiv.com/cap/disgruntled-gmo-firms-start-pull-news-510378 (last accessed on 12 June 2013).

14 TNS Opinion & Social, "Special Eurobarometer 341 on Biotechnology", October 2010, Document requested and coordinated by the European Commission DG Communication, available on the Internet at http://ec.europa.eu/public_opinion/archives/ebs/ebs_341_en.pdf (last accessed 14 June 2013); Leonie Sontheimer, "Märsche mahnen Monsanto", Die Tageszeitung, 25 May 2013, available on the Internet at http://www.taz.de/!116800/ (last accessed on 6 June 2013).

2. Research Approach and Methodology

Our article integrates itself in a line of interdisciplinary research on risk regulation (e.g.: Jasanoff[15], Fisher et al.[16], Everson & Vos, Van Asselt[17], Versluis & Vos[18], Van Asselt & Vos[19]). Risk regulation has an impact on various domains such as environment, trade, jurisdiction and the public and is therefore a highly complex issue. As the topic of our article overarches numerous domains such as trade in a globalized world, society, science and technology as well as legal sciences, an interdisciplinary approach is not only suitable but also thought provoking to answer the question of unlocking the deadlocks. With the words of Van Asselt and Vos "interdisciplinary research in law and social sciences allows for an improved examination of regulatory arrangements"[20] and according to us also stimulates new ideas.

Whereas the former is evident in the comprehensive analytical part of our article, the latter is especially visible in the section of our solution to the deadlocks.

By combining a social sciences approach with a legal analysis, we aim at answering our research question as precise and thorough as possible. As pointed out by Van Asselt and Vos, it strengthens and completes the analysis when social scientists take account of the legal context and lawyers examine the answers of social sciences with the lenses of their educational background.[21] Since we investigate a deadlock caused by societal, scientific and legal problems, it is not only interesting but also necessary to examine the conflict from several points of view.

Whereas the beginning of our article presents an opportunity for legal scholars to grasp the issues at stake from a social sciences point of view, later sections on the legal analysis

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15 Sheila Jasanoff, *Designs on Nature: Science and Democracy in Europe and the United States*, (USA: Princeton University Press, 2005).

16 Elizabeth Fisher, Judith Jones & René von Schomberg, (eds), *Implementing The Precautionary Principle – Perspectives and Prospects*, (UK: Edward Elgar Publishing Limited, 2006).

17 Michelle Everson & Ellen Vos, "The Scientification of Politics and the Politicisation of Science", in Michelle Everson & Ellen Vos (eds.), *Uncertain Risks Regulated. Facing the Unknown in National, EU and International Law*. (London and New York: Routledge, 2009), pp.1-17.

18 Marjolein B.A. Van Asselt, Esther Versluis, & Ellen Vos (eds.), *Balancing between trade and risk: Integrating legal and social science perspectives*, (London, UK: Routledge, 2013).

19 Marjolein B.A. Van Asselt & Ellen Vos, "Wrestling with Uncertainty: EU Regulation of GMOs and the Uncertainty Paradox", 11, *Journal of Risk Research*, 2008, pp. 281-300.

20 Marjolein B.A. Van Asselt, Tessa Fox, Esther Versluis & Ellen Vos, "Regulating Innovation, Trade and Uncertain Risks", in Marjolein B.A. Van Asselt, Esther Versluis, & Ellen Vos (eds.), *Balancing between trade and risk : Integrating legal and social science perspectives*, (London, UK: Routledge, 2013), pp.247 et *sqq*. at p.248.

21 Van Asselt et al., Balancing between Trade and Risk, *supra* note 20, at p.248.

of the proposal aim at providing the social scientist with a complete and understandable overview of possible conflicts in the legal domain.[22] Moreover, our policy proposal, developed on knowledge of both fields – social sciences and legal studies - shows that the deadlocks might only be unlocked if both fields carefully listen to each other and take into account each others' difficulties. It is of utter importance that on the one hand "legal scholars remind social scientists to take serious account of legal frameworks and realities". On the other hand, legal scholars need "to consider the societal dimensions of risk controversies and trade conflicts as wel as the socially constructed nature of expertise".[23]

Therefore, we draw conclusions from close reading of primary sources such as EU and WTO legislation, case law as well as newspaper articles from different Member States, but also scholarly research done in the same context.[24] In order to move a step forward towards unlocking the deadlocks, the legal framework of a particular risk regulation is examined with lenses from political and social sciences (as has been done *inter alia* by: Fox et al.[25], Van Asselt[26]) as well as scholarly work by science and technology scholars (for consultation see: Fox et al., Wickson & Wynne[27], Devos et al.[28]).

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22 Ibid.

23 Ibid.

24 for reference see: Maria Weimer, "What Price Flexibility? - The Recent Commission Proposal to Allow for National "Opt-Outs" on GMO Cultivation under the Deliberate Release Directive and the Comitology Re form Post-Lisbon", 4, *European Journal of Risk Regulation* (2010), pp.345 et *sqq.*; Fern Wickson & Brian Wynne, "The Anglerfish deception - The light of proposed reform in the regulation of GM crops hides underlying problems in EU science and governance", 13, *European Molecular Biology Organization Reports*, (2012), pp.100 et *sqq.*

25 Tessa Fox, Esther Versluis & Marjolein B.A. Van Asselt, "Regulating the Use of Bisphenol A in Baby and Children's Products in the European Union: Trade Implications of an Uncertain Risk" in: in Marjolein B.A. van Asselt, Esther Versluis, & Ellen Vos (eds.), *Balancing between trade and risk : Integrating legal and social science perspectives*, (London, UK: Routledge, 2013), pp.147 et *sqq.*

26 Van Asselt et al., Balancing between Trade and Risk, *supra* note 20.; Marjolein B.A. Van Asselt, Ellen Vos & B. Rooijackers, "Science, Knowledge and Uncertainty in EU Risk Regulation", in Michelle Everson & Ellen Vos (eds.), *Uncertain Risk s Regulated. Facing the Unk nown in National, EU and International Law*, (London and New York: Routledge, 2009), pp.1-17.

27 Fern Wickson & Brian Wynne, "Ethics of Science for Policy in the *Environmental* Governance of Biotechnology: MON810 Maize", 15, *Europe, Ethics, Policy & Environment*, (2012), pp. 321 et *sqq.*; Fern Wickson & Brian Wynne, "The Anglerfish deception - The light of proposed reform in the regulation of GM crops hides underlying problems in EU science and governance", 13, *European Molecular Biology Organization Reports*, (2012), pp.100 et *sqq.*

28 Yann Devos, Pieter Maeseele, Dirk Reheul, Linda van Speybroeck, & Danny de Waele, "Ethics in the societal Debate on Genetically modified organisms: A (re)quest for sense and sensibility", 21, *Journal of Agricultural and Environmental Ethics*, 2008, pp. 29 et *sqq.*

Interdisciplinary scholarly work (see Everson & Vos[29], Hristova[30], Zurek[31], Van Asselt, Versluis & Vos[32]), as well as legal scholars working on the same topic (in particular see: Weimer[33], Vos[34]) have contributed to this research area.

Nevertheless, it is important to keep in mind that we do not aim at pointing out the contrasts of different sciences but rather attempt to complement them in our proposal. In this regard interdisciplinary work seems to be the only solution to move forward. The combination of our educational backgrounds in law, social sciences and political sciences adds to the interdisciplinary nature of this article.

3. The Former Authorization Procedure and the Importance of Science

The first deadlock on GMO authorization has its origins in the complex interplay of scientific risk assessors and political risk managers. This section aims at providing a short overview of the authorization process to consequently analyse the first deadlock. Two legislative acts govern the former regulatory framework on the GMO authorization

29 Everson & Vos, The Scientification of Politics and the Politicisation of Science, *supra* note 17.

30 Vessela Hristova, "Between Politics and Science. Accommodating National Diversity in GMO Regulation", in Marjolein B.A. Van Asselt, Esther Versluis & Ellen Vos (eds.), *Balancing between trade and risk : Integrating legal and social science perspectives*, (London, UK: Routledge, 2013), pp.107 et *sqq*.

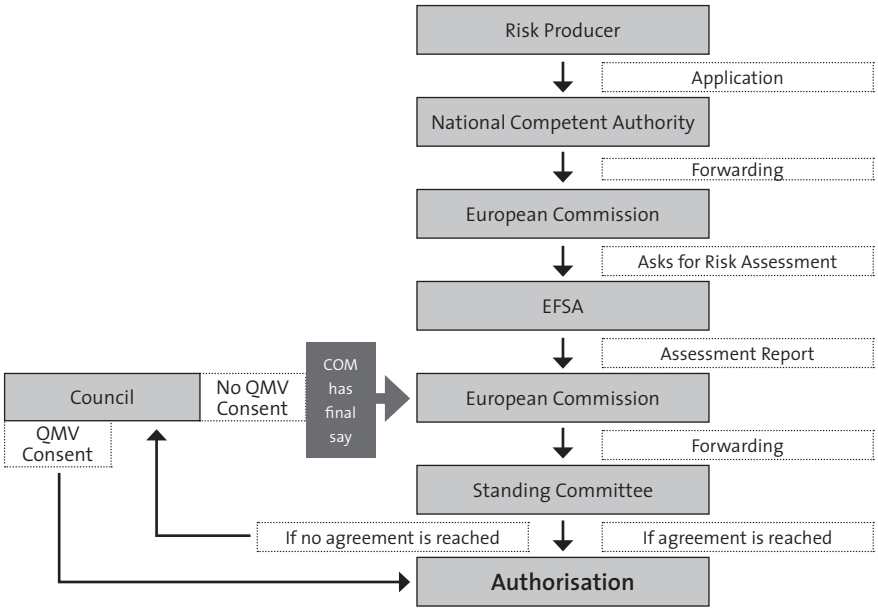
31 Karolina Zurek, "Regulating Food Trade in the Enlarged European Union", in Marjolein B.A. Van Asselt, Esther Versluis, & Ellen Vos (eds.), *Balancing between trade and risk : Integrating legal and social science perspectives*, (London, UK: Routledge, 2013), pp. 15 et *sqq*.; Karolina Zurek, "Indicating Reasons for National GM "Opt-Outs": The Way Forward or a Dead End Street?", 2, *European Journal of Risk Regulation*, (2011), p. 241 et *sqq*.

32 Van Asselt et al., Balancing between Trade and Risk, *supra* note 20.

33 Maria Weimer, "EU Risk Governance of 'Cloned Food'", in Marjolein B.A. van Asselt, Esther Versluis & Ellen Vos (eds.), *Balancing between trade and risk: Integrating legal and social science perspectives* , (London, UK: Routledge, 2013), pp.33 et *sqq*.

34 Maria Weimer, "What Price Flexibility? - The Recent Commission Proposal to Allow for National "Opt-Outs" on GMO Cultivation under the Deliberate Release Directive and the Comitology Reform Post-Lisbon", 4, *European Journal of Risk Regulation* (2010), pp.345 et *sqq,* at p. 345.

procedure in the EU.[35] While the Directive 2001/18/EC[36] regulates the deliberate release of GMOs as products or as part of products on the market, Regulation 1829/2003[37] applies to GM food and feed. Before being merchandised, a GMO seed needs to pass a scientific risk assessment of potential effects on human health and the environment under the Directive.[38] The agency EFSA was established in reaction to the *de facto* moratorium as an independent and objective risk assessor to provide the EU and its Member States "with the best possible scientific opinions in al cases".[39]



Graph 1 Notification procedure for GMO authorization under Directive 18/2001/EC

35 Since Regulation 182/2011 is in effect, the comitology procedure has changed so that "only the comitology committee composed of representatives of national administrations will be able to approve or reject the draft acting with a qualified majority of its members", see in Weimer, What Price Flexbility?, *supra* note 34. Therefore, the comitology procedure was reduced to a two stage one. However, as the procedure before has led to the first deadlock, we describe the former one in this section.

36 Directive 2001/18/EC, *supra* note 3.

37 European Parliament and Council Regulation (EC) No 1829/2003 on genetically modified food and feed, OJ 2003 L 268.

38 Directive 2001/18/EC, *supra* note, Art. 1.

39 Regulation 178/2002, *supra* note, Art. 23 (a).

The placement of a GMO on the internal market must be preceded by the notification procedure laid down in Directive 2001/18/EC and presented in Graph 1. The GM-company needs to notify the national competent authority (the national risk assessor) of the Member State where it first wants to market the product.[40] The authority assesses the notification and indicates whether the product is scientifically safe for human health and the environment.[41] EFSA writes its opinion by drawing on national authorities' risk assessments.[42] After the Commission and the Member States have received EFSA's risk assessment, a standing committee decides on the GMO authorization.[43] If no Member State objects the placing on the market, the initial risk assessor gives written consent to the GM-company merchandise the product.[44]

In the case that all Member States do not mutually recognize the risk assessment, a qualified majority needs to be found in the Council. The decision maker of last resort is the Commission, usually accepting the authorizations.[45] A Member State can stil ban "the use and/or sale"[46] of an already authorized GMO by evoking the safeguard clause[47] of Directive 2001/18/EC.[48] Coherence of the authorization standards to resort to natural sciences is guaranteed, as this clause requires the submission of new and additional scientific information on potential adverse effects of that GMO on human health and the environment. The Member State must inform the Commission and the other Member States as well as the public.[49] A decision at EU level must first be taken in the committee again. If no agreement is reached, the draft decision is forwarded to the Council.[50] In the case that still no consent can be found here either, the Commission can directly request a

40 Directive 2001/18/EC, *supra* note 3, Art. 13.2.

41 Directive 2001/18/EC, *supra* note 3, Art. 14.3.

42 Maria Lee, *EU Regulation of GMOs. Law and Decision Making for a New Technology* , (Cheltenham: Edward Elgar, 2009), at p. 67.

43 Lee, *EU Regulations of GMOs*, *supra* note 42, at p. 66.

44 Directive 2001/18/EC, *supra* note 3, Art. 15.3.

45 "It should be noted that under the regulatory procedure so far all authorisation decisions drafted *by* the Commission reached the Council stage, and finally were adopted by the Commission by default", Weimer, What Price Flexbility?, *supra* note 34, at p. 351.

46 Directive 2001/18/EC, *supra* note 3, Art. 23.1.

47 Directive 2001/18/EC, *supra* note 3, Art. 23.

48 Before, the safeguard clause was laid down in Directive 90/220/EEC, which was the predecessor of Directive 2001/18/EC.

49 Directive 2001/18/EC, *supra* note 3, Art. 23.1.

50 Directive 2001/18/EC, *supra* note 3, Art. 23.1.

Member State to revoke the ban, as described below. Generally, it is essential to note that the entire authorization procedure is based on the assessment of the outcome of natural sciences studies and the interpretation of this assessment by risk management. Risk regulation thus always resorts to natural sciences as an 'arbiter' between risk assessors, on the one hand, and risk managers, on the other hand.

3.1 The Authorization Procedure in Practice – the First Deadlock

As shown above, the authorization procedure resorts to natural science to create reliable and accurate standards. In practice, however, the authorization procedure has developed into a heated debate both at the national and the EU level since national bans on cultivation and imports have been disputed for over a decade.[51] Austria, for example, continuously voted against GMOs in the Council and persistently evoked the safeguard clause to ban GMO marketing and cultivation.[52] It was the first Member State to ban MON810[53] after Monsanto's application for marketing the GMO in France and the subsequent authorization of cultivation in 1998.[54] The Austrian risk assessor justified the ban with potential adverse effects on human health and the environment[55], emphasising scientific uncertainty as the main reason.[56] [57] In the wake of the Austrian import ban of MON810, five Member States issued a declaration cal ing "for the adoption of a more rigorous and transparent

51 EurActiv, "GMO debate continues to divide EU", 15 April 2013, available on the Internet at http://www.euractiv.com/climate-environment/gmo-debate-continues-divide-eu-news-219382 (last accessed on 14 June 2013).

52 GMO-free regions 2012, "Austria", no date, available on the Internet at: http://www.gmo-free- regions.org/gmo-free-regions/austria.html (last accessed on 6 June 2013).

53 In 1999, Austria evoked the safeguard clause under Directive 90/220/EEC Art. 16, which preceded Directive 2001/18/EC, *supra* note 52.

54 Bundesgesetzblatt für die Republik Österreich, Teil II: Verordnungen, 1999. 175. Verordnung: Verbot des Inverkehrbringens des genetisch veränderten Maises *Zea Mays* L., Linie MON 810, in Österreich.

55 Bundesministerium für Gesundheit und Frauen (1999). Gründe für die Entscheidung der Republik Österreich, das Inverkehrbringen der gentechnisch veränderten Maislinie MON810, notifiziert von der Fa. Monsanto Europa SA gemäß der Richtlinie 90-220/EWG und zugelassen von der Französischen Republik am 5. August 1998, zu verbieten. Available on the Internet at http://bmg.gv.et/cms/home/attachments/2/2/5/CH1060/CMS1212741055132/mon810_begruendung.pdf (last accessed on 14 June 2013), at pp. 2-4.

56 "as long as newly emerging uncertainties in the assessment are not finally resolved, Austria has reason to believe that the cultivation of the product MON810 constitutes a risk for human health and the environment", see BMFG, *supra* note 55, at p. 5.

57 Bundesgesetzblatt für die Republik Österreich, Teil II: Verordnungen, 1999. 175. Verordnung: Verbot des Inverkehrbringens des genetisch veränderten Maises Zea Mays L., Linie MON 810, in Österreich.

regulatory framework."[58] The resulting *de facto* moratorium brought authorization of GM foods for marketing in the EU to a halt[59] and was only lifted in 2004, after Directive 2001/18/EC and Regulation 1829/2003 were in effect and EFSA[60] was established.[61]

Austria, however, stayed persistent and forwarded further information to the Commission regarding its national import ban on MON810. EFSA reacted by issuing a new assessment and declared that its risk assessment is still valid as Austria did not provide new scientific insights. Thus, the Commission concluded that Austria must revoke the import ban on MON810. In 2005, the Council, nevertheless, rejected the Commission's proposal to take action against Austria with a qualified majority. Furthermore, it persistently took the stance that scientific uncertainty about the risks of MON810 was still prevalent and that a consideration of whether the national import ban could be justified as a precautionary measure was appropriate.[62] Although EFSA and the Commission declared the cultivation of MON810 to be safe once more, other Member States joined Austria in evoking the safeguard clause to ban the GMO.[63] The failure to come to an agreement "can at least partly be explained by the fact that Member States' interests are not reflected fully at the risk assessment stage".[64] We define this stalemate as the first deadlock as this obvious clash between the Member States' and the Commission's needs hindered the procedure of authorization of GMOs significantly.

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58 Joachim Scholderer, "The GM foods debate in Europe: History, regulatory solutions, and consumer response research", 5, *Journal of Public Affairs*, (2005), pp. 263 et *sqq*., at p. 267 – the Member States were Denmark, France, Greece, Italy and Luxembourg.

59 Scholderer, "The GM foods debate in Europe", *supra* note 58, at p.267.

60 EFSA was created with the aim to create more accurate and reliable standards for GMO authorization across the EU- see Directive 2001/18/EC *supra* note 3, Art.4.3 and Regulation 178/2002 *supra* note 4, Art. 23 (j).

61 Scholderer, "The GM foods debate in Europe", *supra* note 58, at p.268.

62 Kommission, Entscheidung der Kommission über das vorübergehende Verbot der Verwendung und des Verkaufs von genetisch verändertem Mais (*Zea mays* L., Linie MON810) gemäß der Richtlinie 2001/18/EG des Europäischen Parlaments und des Rates in Österreich, K (2008) 1718.

63 GMO-free Europe 2012, "GE cultivation bans in Europe", no date, available on the Internet at: http://www.gmo-free-regions.org/gmo-free-regions/bans.html (last accessed on 4 June 2013); EurActiv, "Bulgaria approve law to ban GMO crops", 5 November 2012, available on the Internet at: http://www.euractiv.com/cap/bulgaria-approves-law-ban-gmo-cr-news-355729 (last accessed on 4 June 2013) - Member States banning GMOs until 2010 were: Austria, France, Greece, Hungary, Germany, Luxembourg and Bulgaria.

64 Jinhee Kim, Christoph Klika, & Esther Versluis, "Agencies as Risk Managers? Exploring the role of EU agencies in authorization procedures", in Marjolein B.A. van Asselt, Esther Versluis & Ellen Vos (eds.), *Balancing between trade and risk : Integrating legal and social science perspectives*, (London, UK: Routledge, 2013), pp. 175 *et sqq*.; at p.191.

3.1.a External and Internal Repercussions of the First Deadlock

The importance of reforming the authorization procedure became more important as the clash between EFSA and Austria's national competent authority expanded to the international sphere. When the USA, Canada and Argentina argued in the *EC Biotech* case that the national import bans in the EU were not in line with the WTO rules on free trade, the WTO Panel in charge[65] stated that the import bans were indeed illegal. The main reason for this ruling was that Austria's risk assessment did not conform to WTO requirements for scientific risk assessments.[66] In 2007, Austria issued a revised risk assessment in which it defended the banning of gene maize in light of the WTO dispute. The assessment restated the adverse effects argument, but also included economic losses to the organic farming sector as a reason to ban MON810.[67] This was the first risk assessment that expanded its argumentation to 'non-risk'[68] issues and in particular to socio-economic grounds.[69]

At the EU level, the Council resumed these new grounds in their argumentation. In its statement on the Austrian ban it stresses that risk assessment should take agricultural structural differences as well as regional ecological characteristics into account.[70] Since the Council failed to agree on the legality of Austria's ban, the Commission directly requested Austria to al ow the cultivation and marketing of MON810 in 2008. This time, the Commission explicitly referred to the ban to import and process MON810 in Austria, but left the issue of cultivation unmentioned.[71] Austria, however, repealed the ban only

65 Michael Eckerstdorfer, Andreas Heissenberger & Helmut Gaugitsch, *Supplementary Risk Assessment for GM Maize MON810 with regard to the conclusions of the WTO-Panel in the case "EC Biotech" on Austrian safeguard measures for GM Maize,* (Wien: Bundesministerium für Gesundheit, Familie und Jugend, Sektion IV, 2007).

66 World Trade Organisation (2006). European Communities – Measures Affecting the Approval and Marketing of Biotech Products (WT/DS291/R, WT/DS292/R, WT/DS293/R). Reports of the Panel. available on the Internet at: http://www.worldtradelaw.net/reports/wtopanelsfull/ec-biotech(panel)(full).pdf (last accessed on 14 June 2013).

67 Eckerstdorfer, Heissenberger & Gaugitsch, Assessment for MON810, *supra* note 65, at pp. 23-25.

68 Brian Wynne, "Elephants in the room where publics encounter 'science'?: A response to Darrin Durant 'Accounting for expertise: Wynne and the autonomy of the lay public'" in 17, *Public Understanding of Science*, (2008), pp. 21 et *sqq*.: – Such reasons are called 'non-risk' issue in this context, since they are not primarily about threats to human health or the environment, but comprise a myriad of public issues about new technologies.

69 According to Weimer, the term 'socio-economic' is not clearly defined in this respect, see Weimer, What Price Flexbility?, *supra* note 34.

70 Entscheidung der Kommission über Verbot von MON810, *supra* note 62.

71 Entscheidung der Kommission über Verbot von MON810, *supra* note 62.

to issue a new one on the import of gene maize.[72] Austria's revised risk assessment and the subsequent Council statement show a development to expand beyond a traditional risk assessment based on natural sciences. The latter could not do justice to its 'arbiter' role attributed to them in the risk assessment process. Moving to 'non-risk' issues such as socio-economic reasons elucidates that grounds that could not be assessed permeated the GMO controversy. Due to scientific uncertainty, no accurate and reliable answer seemed possible which caused the continuous bargaining between risk assessors and managers at the national and EU level. Thus, this lengthy and complicated negotiations regarding scientific evidence in the risk assessment, blocked the Commission and the Member States in the first deadlock. After showing that science was not able to serve as an 'arbiter', we analyse the problems of sciences in risk assessment and scientific uncertainty in particular.

4. Science as Solution to the First Deadlock?

Even though the whole GMO authorization process is based on scientific evidence, it is visible from the section above that the recourse to natural sciences did not provide a solution to the first deadlock. Logically the question arises to what an extent in general science is able to solve the first deadlock? As we have seen, natural sciences examining health and environmental effects of GMOs do not provide clear answers, but instead risk assessors infinitely debate the different outcomes of scientific studies. We argue that there are several reasons why in risk regulation, especially regarding GMOs, science cannot solve the deadlock: First, science in itself is flawed; second, the role of risk assessment in the authorization process is inadequate and places science in a role that it simply cannot fulfil; third, the ambiguous role of science in risk management make it impossible for science to be the solution to the deadlock.

4.1 The Unreliability of Scientific facts

Scientific facts "are nothing but answers to questions that could have been asked differently".[73] This quote by the sociologist Beck describes precisely one of the main problems for science in its imposed role of being a neutral arbiter in risk assessments.

72 Bundesgesetzblatt für die Republik Österreich, Teil II: Verordnungen, 2008. 181. Verordnung: Aufhebung des Verbots des Inverkehrbringens des gentechnisch veränderten Maises Zea mays L., Linie MON 810 sowie erneutes Verbot des Inverkehrbringens dieser Maislinie zum Zweck des Anbaus in Österreich.

73 Ulrich Beck, *Risk Society: Towards a New Modernity* (London: Sage, 1992), pp.166-68.

Unfortunately, differing research questions are not the only problem of scientific studies. Possibly due to a lack of a common regulatory framework for good practice[74], each scientific study can be based on different methodologies and research designs.[75] In the context of GMO assessment this explains why some scientific studies conclude that cultivation is non-problematic whereas others find potential hazards. We argue that the lacks of a common regulatory framework on EU level is not the only problem, there is arguably also a problem of objectivity: the bioethical scientist Rossi states bluntly that "objectivity in risk assessment would require objectivity *at each* of the subsidiary evaluative levels, and ..., there are numerous reasons to doubt that such an objective standard can be elaborated at present".[76] Regarding the important role of science in risk assessment, we claim that its problem of objectivity also holds true for the whole scientific assessment process of GMOs.

Nonetheless, we argue that not only science is sometimes not entirely objective, but moreover it is important to see which values and norms determine the focus of the scientific study, as these might influence the outcome.[77] Therefore, even decisions entirely based on science are not free of any subjective value, in line with Rossi's argument that to be value free and entirely objective, each stage of the entire process needs to objective.[78] This is not easily done, especially regarding a hot topic such as GMOs. Taking together these issues with science, it is not astonishing that the outcomes of scientific studies for risk assessment are not always the same and sometimes not even comparable. Conclusions drawn from these studies need to be debated within the scientific and political community, as science seems not to be able to fulfil the role of being the ultimate decision-basis. Moreover, these problems with science as such show that differing outcomes in scientific risk studies do not necessarily establish concrete risk. It might only indicate that the scientific study has addressed the topic with another research question or scientific method. Conclusively, this also shows that science is probably unable to provide an absolute basis for EU-wide policies or as sole basis for risk regulation. Moreover,

74 Fern Wickson & Brian Wynne, "Ethics of Science for Policy in the Environmental Governance of Biotechnology: MON810 Maize", 15, *Europe, Ethics, Policy & Environment*, (2012), pp. 321 et *sqq*.

75 Wickson & Wynne, Ethics of Science for Policy in the Environmental Governance of Biotechnology, *supra* note, at p. 323.

76 John Rossi, "The Prospects of Objectivity in Risk Assessment", 46, J Value Inquiry (2012), pp. 237 et *sqq*. (emphasis added).

77 Fern Wickson & Brian Wynne, "Ethics of Science for Policy in the Environmental Governance of Biotechnology: MON810 Maize", 15, Europe, Ethics, Policy & Environment, (2012), pp. 321 et *sqq*., at p.328.

78 Susan Carr & Les Levidow, "Exploring the Links Between Science, Risk, Uncertainty, And Ethics In Regulatory Controversies About Genetically Modified Crops", 2, *Journal of Agricultural and Environmental Ethics,* (2000), pp.29 *et sqq*., at p.32; Devos et al., "Ethics in the societal Debate on Genetically modified organisms", *supra* note 28, at p.46

it clarifies how the requirement of new and additional scientific evidence might not be adequate to justify a ban. Nonetheless, the Precautionary Principle states that the risk assessment only has to be taken into account by the risk manager.[79] This touches upon another reason why science cannot be the solution to the deadlock: as analysed by looking into science's role in risk assessment in the EU's framework on risk regulation.

4.2 Science's role in risk assessment

During the authorization process, the potential risks of a GMO are addressed in risk assessments, which are conducted at the national and EU level, by the national authorities and EFSA.[80] The possibility to argue with numerous studies that differ in their judgements on the potential risk of GMOs for humans and the environment leads to yet another factor, explaining why natural sciences cannot be the solution to the deadlock. In risk regulation in general, and also in the GMO authorization process, the uncertainty paradox as established by Van Asselt and Vos is persistent.[81] Scientific uncertainty manifests itself when science cannot deliver finite answers. Scientific uncertainty is defined in this article as a situation where "scientific or historic proofs of harmful consequences are lacking, but suspicions cannot be fully refuted either".[82] The uncertainty paradox is produced by risk assessor, EFSA and risk managers, such as the Commission, when they demand concrete scientific evidence[83], whereas this is arguably not possible in a situation of scientific uncertainty.[84]

Scientific uncertainty has the potential to lead to "irresponsible attenuation of the risk, sustained controversy, deadlocks, legitimacy problems, unintelligible decision-

79 Commission Communication on the precautionary principle, COM(2000)1.

80 "it was accepted that scientific expertise should be pluralized in risk assessment in order to render more explicit which value judgments about the acceptability of harm are et play, and to take into account the permanent interplay between risk assessment and risk management. That risk assessments conducted by various European and national expert committees often give different outcomes is illustrative of the fact that various interpretations are given, values and ideals held, institutional cultures detained, and precautionary accounts taken." In Devos et al., "Ethics in the societal Debate on Genetically modified organisms", *supra* note 28, at p.46.

81 Marjolein B.A. Van Asselt & Ellen Vos, "The Precautionary Principle and the Uncertainty Paradox", 9, *Journal of Risk Research* (2006), pp.313 et *sqq*.

82 Marjolein B.A. Van Asselt & Ellen Vos, "Wrestling with uncertain risks: EU regulation of GMOs and the uncertainty paradox", 11, *Journal of Risk Research,* (2008), pp.281 et *sqq*.

83 Anne-May Janssen & Marjolein B.A. van Asselt, "The Precautionary Principle in Court – An Analysis of Post-Pfizer Case Law", in Marjolein B.A. van Asselt, Esther Versluis & Ellen Vos (eds.), *Balancing between trade and risk : Integrating legal and social science perspectives*, (London, UK: Routledge, 2013), pp.197 *et sqq.*, at p.197.

84 Van Asselt & Vos, Wrestling with uncertain risks, *supra* note 82.

making, trade conflicts, border conflicts [and] expensive re-bound measures".[85] Most of these outcomes can be seen in the section describing the first deadlock. In the case of GMOs, risk assessors expect a clear statement by scientists about the potential harmful effects of the product in question. Moreover, under the regulatory framework of Directive 18/2001/EC, only new and additional scientific evidence justifies a ban. However, as the example of Austria above illustrates, this scientific evidence brought forward is always rejected by EFSA. Therefore, we argue that not only flaws within science but also scientific uncertainty make it impossible for science to solve the first deadlock. Alas, even another tension exists regarding science, risk management and the role of science.

4.3 Science's role in Risk Management

Although risk assessment is formally separated from risk management, the scientific risk assessment implicitly guides the risk manager in its decision.[86] In line with our argumentation and according to Jasanoff, a scholar in the field of science and technology the legal framework should appoint risk assessment the role of "inject[ing] much needed competence and critical intel igence into a system otherwise al too vulnerable to the demands of politics."[87] As the risk manager, the Commission has to ensure that all differing outcomes between national and EU-level assessments and the opinions of different stakeholders are accommodated in the risk measure. Moreover, GMOs are a highly debated topic: although scientists do not yet agree which risks and benefits GMOs entail, the two-thirds of European public has a negative attitude towards GMOs.[88] With reference to these miscellaneous stakeholders, another reason of science's inability to solve the deadlock becomes visible: the perception of risk differs between the public and scientists. While "experts describe risk on grounds of strictly scientifically determined standards",[89] the public and politicians also emphasize non-scientific reasons for their cautious stance.[90] Scientists attempt to quantify

85 Marjolein B.A. Van Asselt & Ortwin Renn, "Risk Governance", 14, *Journal of Risk Research*, pp.431 *et sqq*., at p.438.

86 Hristova, V. (2013), Accommodating National Diversity in GMO Regulation. In Marjolein B.A. van Asselt, Esther Versluis & Ellen Vos (eds.), *Balancing between trade and risk : Integrating legal and social science perspectives*, (London, UK: Routledge, 2013), at p.110.

87 Sheila Jasanoff, *The fifth branch: Science advisors as policymak ers*, (Cambridge, MA: Harvard University Press, 1990)

88 Special Eurobarometer 341, *supra* note 14; Devos et al., "Ethics in the societal Debate on Genetically modified organisms", *supra* note 28, at p.30.

89 Devos et al., "Ethics in the societal Debate on Genetically modified organisms", *supra* note 28, at p.30.

90 for reference see: Siegrist, 2000; Marris, 2001; Lassen et al., 2002; Shaw, 2002; Verhoog et al., 2003; Cook et al., 2004; Frewer et al., 2004; Deckers, 2005; Madsen and Sandøe, 2005; Lassen and Jamison, 2006 in Devos et al., "Ethics in the societal Debate on Genetically modified organisms", *supra* note 28, at p.30.

risk, whereas policy makers often hold qualitative assessments of a product's risk. Such an assessment regards GMOs as a risk to cultural values or socio-economic reasons such as traditional farming, native identity, or ethical implications of gene modification.[91] Thus, the risk manager does not only face the problems of science, but also needs to accommodate this division between scientists and public.

Applied to the beforehand-discussed deadlock of GMO authorisation, we argue that stakeholders with strong opinions regarding GMOs (e.g. MS, EFSA, Monsanto) possibly base their arguments on different scientific studies that seem to be tailored to support each stakeholder's particular interest.[92] In other words, Jasanoff holds it: "facts and values frequently merge when we deal with issues of high uncertainty".[93] Even though she argues this in the general context of framing scientific uncertainty, we argue that this also holds true in the debates among stakeholders. According to Knudsen, a biology professor, "politics and science become so intertwined that it can be impossible to separate the scientific questions from the political questions".[94] Conclusively, science might push the deadlock even further when differing outcomes of scientific studies or the insufficiency of providing clear answers is (mis)used by politics.

Consequently, science cannot - and according to us should not [solely] - be used as the ultimate basis for risk regulation in the GMO authorization process. There are too many flaws, uncertainties and tensions attached to it, making it incapable to accommodate all stakeholders.

5. The Second Deadlock: Disagreement on the Proposal

Besides scientific uncertainty with regards to risks and benefits of GMOs, another key element defining the first deadlock on GMO authorization in the EU becomes evident by close analysis of the exact issues at stake. Austria's risk assessment report from 2007,

91 Merkur Online, "Bayern bremst grüne Gentechnik", 9.August 2010, available on the Internet at: http://www.merkur-online.de/aktuelles/politik/bayern-bremst-gruene-gentechnik-mm-871416.html, (last accessed on 14 June 2013); Christian Schwägerl, "Gentechnik: Hier geht es um den Heimatbegriff", 17 October 2010, available on the Internet at http://www.spiegel.de/politik/deutschland/gentechnik-hier-geht-es-um-den- heimatbegriff-a-723550.html (last accessed on 5 June 2013).

92 As was seen in France and Germany - Shane H. Morris & Charles Spillane, "EU GMO Crop Regulation: A Road to Resolution or a Regulatory Roundabout?", 4, *European Journal of Risk Regulation*, pp.359 et *sqq*., at p.363/364.

93 Sheila Jasanoff, "Bridging the Two Cultures of Risk Analysis", 13, Risk Analysis (1993), at p.123.

94 Guy R. Knudsen, "Where's the Beef? How Science Informs GMO Regulation And Litigation", *Idaho Law Review 48*, pp. 225-250, at p.230.

first, lists potential adverse effects of MON810 on human health and the environment.[95] Secondly, however, the report justifies Austria's ban by stating potential adverse effects of MON810 cultivation with reference on Austria's organic agricultural economy.[96] The incorporation of the socio-economic consideration of avoiding GMO presence in other products suggests that socio-economic grounds play a role next to health and environmental concerns in defining a Member State's GMO policy.

Moreover, also in the justifications for the German bans, we identified socioeconomic as well as cultural and ethical considerations on GMO policy. Germany has an organic farming sector proportionately smal er than Austria's.[97] Nevertheless, in 2009, Germany has been the latest Member State to join the ones banning MON810 since the *de facto* moratorium had been ended.[98] Interestingly, the German competent authority justified evoking the safeguard clause with new and additional scientific information on adverse environmental effects of MON810 cultivation. Consequently, the ministry of food, agriculture and consumer protection ordered the competent authority to issue a ban,[99] even though the authority's scientific panel disagreed, stating that there was no scientific evidence for environmental risks of MON810.[100]

This case of Germany shows how the formal distinction between scientific risk assessment and political risk management becomes questionable, when the competent authority disagreed with its own scientific panel. In an interview in 2010, the Bavarian state minister for environment and public health argued that opposition against GMOs was a cultural issue. GMO cultivation would harm regional agricultural structure and contradict local identity. Regional organic farming could not coexist with GMO cultivation. He concluded that GMO cultivation would touch on ethical considerations.[101]

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95 Bundesministerium Für Gesundheit, Familie und Jugend, *supra* note 65, pp.14-22

96 Bundesministerium Für Gesundheit, Familie und Jugend, *supra* note 65, at p.25.

97 Bundesministerium Für Gesundheit, Familie und Jugend, *supra* note 65, at p.142.

98 GMO-free Europe 2012, "GE cultivation bans in Europe", no date, available on the Internet at: http://www.gmo-free-regions.org/gmo-free-regions/bans.html (last accessed on 4 June 2013);

99 Bundesministerium für Ernährung, Landwirtschaft und Verbraucherschutz, (2009). Press release no. 063 from 14.04.2009: Aigner prohibits cultivation of MON810. Available on the Internet at: http://www.bmelv.de/SharedDocs/Pressemitteilungen/EN/063-MON810.html (last accessed on 14 June 2013).

100 Bundesamt für Verbraucherschutz und Lebensmittelsicherheit Abteilung Gentechnik (2009). Bescheid Aktenzeichen 6788-02-13 (C/F/95/12-02). Available on the Internet at http://www.bvl.bund.de/SharedDocs/Downloads/06_Gentechnik/ZKBS/01_Allgemeine_Stellungnahmen_deutsch/04_Pflanzen/MON810_Neubewertung_2009.pdf?__blob=publicationFile&v=3 (last accessed on 14 June 2013).

101 Christian Schwägerl, "Gentechnik: Hier geht es um den Heimatbegriff", 17 October 2010, available on the Internet at http://www.spiegel.de/politik/deutschland/gentechnik-hier-geht-es-um-den-heimatbegriff-a-723550.html (last accessed on 5 June 2013).

Together, the examples of Austria and Germany give a broader picture of possible grounds on which opposition to GMOs can be founded – grounds inaccessible for the natural sciences, which are central to EFSA's risk assessment, as il ustrated above. Underlying reasons, which were not assessed drove Member States to reject GMOs on their territory. Regarding the two cases of Austria and Germany, the 'arbiter' role of science is made yet again impossible by a risk assessment approach, which does not take into account scientific uncertainty and excludes 'non-scientific' grounds, such as socio-economic, cultural and ethical reasons. These grounds are also 'non-risk' issues, since they do not deal with potential threats to human health or the environment. As this section shows, the applications of the safeguard clause were not, or were not primarily about risk, thus, GMOs do not touch primarily on scientific questions. Thus, it is wrong "to cal public issues about new technologies which involve risk but which also involve many other issues, 'risk issues'."[102] In the current regulatory framework, these reasons are legally insufficient to justify a ban, although they play an important role in the political decision-making on GMOs.

Therefore, the proposed Amendment to Directive 2001/18/EC is examined to illustrate the Commission's attempt to resolve the above-described deadlock on GMO authorization. As we have shown with the examples of Austria and Germany, Member States had non-scientific concerns about GMOs, which the new proposal aims to address through the introduction of non-scientific grounds that may be invoked by Member States to justify bans on cultivation of GMOs. After a brief introduction of the proposed amendment, the issues that arose concerning the amendment are discussed.

5.1 The Proposal: A Solution to the Deadlock?

In order to resolve the first deadlock several Member States, regardless of pro- or anti-GMO stances, urged the Commission to propose a reform of the GMO regulatory framework.[103] As a result, the Commission issued an amendment to Article 26 Directive 2001/18/EC. The proposal for a new Article 26b allows the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory on grounds other than health and environment.

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102 Brian Wynne, "Elephants in the room where publics encounter 'science'?: A response to Darrin Durant 'Accounting for expertise: Wynne and the autonomy of the lay public'" in 17, Public Understanding of Science, (2008), pp. 21 et *sqq*, at p.23.

103 The request was made by the Austrian and Dutch delegations supported by Bulgaria, Ireland, Greece, Cyprus, Latvia, Lithuania, Luxembourg, Hungary, Malta, Poland and Slovenia. See for more details: Council Note on the Subject of Genetically Modified Organisms – A Way Forward – Information from the Austrian delegation, 11226/2/09.

'Article 26b Cultivation

Member States may adopt measures restricting or prohibiting the cultivation of all or particular GMOs authorised in accordance with Part C of this Directive or Regulation (EC) No 1829/2003, and consisting of genetically modified varieties placed on the market in accordance with relevant EU legislation on the marketing of seed and plant propagating material, in all or part of their territory, provided that:

(a) those measures are based on grounds other than those related to the assessment of the adverse effect on health and environment which might arise from the deliberate release or the placing on the market of GMOs;

and,

(b) that they are in conformity with the Treaties.

By way of derogation to Directive 98/34/EC, Member States that intend to adopt reasoned measures under this Article shall communicate them to the other Member States and to the Commission, one month prior to their adoption for information purposes.'[104]

According to the Commission, the aim of the proposal is to address specific local or national aspects raised by the cultivation of GMOs by granting Member States an adequate degree of flexibility to decide on GMO cultivation after they have been authorized on EU level.[105] By making it possible for Member States to invoke grounds that are not related to health or environment as justifications for the limitation of GMO cultivation the proposal aims directly at unlocking the decision making deadlock. This is the case as the proposal attempts to advance the reliability of the decisions on GMO authorization for the

104 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, C(2010) 380 final, C(2010) 4822 final, et Art. 1.

105 Commission Proposal for a Regulation of the European Parliament and of the Council Amending Directive 2001/18/EC, *supra* note 8, at pp. 3-6.

stakeholders involved by reducing the likelihood of the invocation of the safeguard clause by Member States. However, since 2011 the proposal has been discussed in the Council by four presidencies[106] and so far three revised compromise proposals have failed to reach a qualified majority on the issue.[107] In addition to the political ordeal of the proposal's many draft amendments, the Commission proposal to amend Directive 2001/18/EC[108] raised several legal concerns in its wake. One of the concerns raised by a blocking minority of Member States is the possible clash of such cultivation bans on socio-economic grounds[109] with WTO and EU law.[110]

Through the creation of the possibility to legally ban GMO cultivation on socio-economic grounds the proposal could provide – at least to a certain extent – a solution to the above-discussed first deadlock concerning the reliance on scientific justifications for the limitation of GMOs by certain Member States. However, due to the Member State opposition in the Council, a second deadlock has been created concerning this potential solution of the first deadlock. While the permission of non- scientific grounds appears to be an ideal solution, especially in light of the above-discussed issues of Member States concerning GMO cultivation, the question arises whether it is indeed legally feasible.

106 These four presidencies were the Belgian, Hungarian, Polish and Danish presidencies.

107 The Hungarian, Polish and Danish presidencies each have created a new revised compromise version of the proposal, all of which in turn have failed to reach the qualified majority needed. See: For the Hungarian Presidency revised compromise proposal: Council of the European Union 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 – Preparation for the Informal Trialogue. 20010/0208 (COD) 10532/11. Polish presidency: Council of the European Union 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 – State of play. 2010/0208 (COD), 17634/11. Danish presidency: Council of the European Union 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 – Revised Compromise Proposal in View of a Council Political Agreement (First Reading). 2010/0208 (COD) 7153/12.

108 Commission Proposal for a Regulation of the European Parliament and of the Council Amending Directive 2001/18/EC, *supra* note 8.

109 The term socio-economic grounds still lacks clarity, see: Commission Report to the European Parliament and the Council on Socio-Economic Implications of GMO Cultivation on the Basis of Member States Contributions, as Requested by the Conclusions of the Environment Council of December 2008. Brussels, COM(2011) final.

110 This blocking minority consists of DE, FR, UK, and BE. See: Council of the European Union "I/A" Item Note on the 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, 108883/1/12, at p. 5.

In order to better understand whether the proposal could provide a solution for the untangling of the second deadlock, the legal issues that have appeared problematic with regard to the Commission's proposal are important to examine. These legal problems formed one of the main concerns of the Member States in the Council, and were thus leading to the deadlock as one of the heated subjects of discussion. Thus, this chapter aims to answer how far this proposal is legally viable. The compatibility of the proposal with EU internal market rules, and specifically the list of grounds invocable by Member States is first discussed. Furthermore, possible conflicts with WTO regulations concerning the proposal are also examined.

5.2 EU Internal Market Compatibility

In order to determine the proposal's compatibility with EU law, the effect of the restriction or prohibition of the cultivation of GMOs on the internal market needs to be taken into consideration. The issue of such compatibility was first raised by the ad hoc working party established by COREPER to consider the Commission's original version of the proposal.[111] [112] Later on the question was also one of the main factors discussed both in the EP as well as in the Council, with special regard to the need for a clear list of grounds that may be invoked.

While the purchase of GM seeds would thus not be prohibited, in practice cultivation limitations would have an indirect effect on the free circulation of GM seeds.[113] This way, the free circulation of goods could be hindered (Article 34 Treaty on the Functioning of the European Union (TFEU)). Hence, Member States attempting to restrict the cultivation of GMOs must ensure that the measure is justified by one of the exceptions of Article 36 TFEU - most likely 'on grounds of public morality, public policy or public security' -, or any other compulsory requirements based on the case law of the Court of Justice of the European Union (CJEU) or secondary legislation. The reasons relating to the public interest which Member States could invoke to restrict or prohibit GM cultivation thus needs to be clarified. However, according to the court's judgement in *Decker* the free movement

111 Council Press Release of the 3075th Council Meeting, 7689/11, at p. 8.

112 Commission Staff Working Document on the Considerations on Legal Issues on GMO cultivation raised in the opinion of the Legal Service of the Council of the European Union of 5 November 2010, SEC(2010) 1454 final, at p. 3.

113 Commission Staff Working Document on the Complementary Considerations on Legal Issues on GMO Cultivation Raised in the Opinions of the Legal Service of the Council of the European Union of 5 November 2010 and on the Legal Service of the European Parliament on 17 November 2010 (Indicative List of Grounds for Member States to Restrict or Prohibit GMO Cultivation), SEC (2011) 184 final, at p. 2.

of goods may not be restricted by 'purely economic' goals.[114] The grounds also must be in accordance with the general common market exemptions criteria of being justified, proportionate and non-discriminatory.

According to the proposed Article 26b, the national measures must be based on grounds other than environmental and health risk assessments, thus formulating a negative definition of admissibility.[115] The phrasing of the proposal suggests that the socio-economic aspect of GMO cultivation is referred to, which - due to its broad meaning lacking specific examples - has been criticized as lacking clarity. This varied list of grounds thus created through the negative formulation of the Commission appears to indicate that by creating wide-ranging possibilities for Member States to deviate from the general EU authorization of cultivation, the proposal attempts to reduce the scope of harmonization of the legal framework on GMO cultivation.[116] Due to the ambiguity of the negative formulation of grounds found in the original proposal, the Commission Services released a non- exhaustive list of possible grounds that could be invoked to limit the cultivation of GMOs.[117] The seven grounds listed by the Commission Services were the following: "public morals, public order, avoiding GMO presence in other products, social policy objectives, town and country planning or land use, cultural policy and general environmental policy objectives, other than assessment of the adverse effects of GMOs on the environment."[118] As six grounds out of the seven indicated in the list of the Commission are socio-economic in their nature, the division between scientific assessment, that is environmental and health concerns, and socio-economic evaluation is demonstrated.

Consequently, as emphasis is placed on socio-economic grounds, it is helpful to examine the Member States assessment of the socio-economic impact of GMOs. The Commission report on the socio-economic implications of GMO cultivation[119] found - on the basis of Member States' contributions - that the perception of the definition of socio-economic dimension of GMO cultivation deviates greatly between the Member States and

114 Case C-120/95, Decker 1998 ECR 1831, at para. 39.

115 Weimer, What Price Flexbility?, *supra* note 34, at p.348.

116 Weimer, What Price Flexbility?, *supra* note 34, at p.348.

117 Commission Staff Working Document on the Complementary Considerations on Legal Issues on GMO Cultivation *supra* note 113.

118 Commission Staff Working Document on the Complementary Considerations on Legal Issues on GMO Cultivation *supra* note 113, at p. 2.

119 Report from the Commission to the European Parliament and the Council on Socio-Economic Implications of GMO Cultivation on the Basis of Member States Contributions, as Requested by the Conclusions of the Environment Council of December 2008. Brussels, COM(2011) final.

the various stakeholders. The main focus of the submissions of the Member States entails the co-existence of GM and organic methods starting with the cultivation of seeds all the way to the end products reaching the shelves, although the greatest focus of the study was directed towards initial part of the process concerning cultivation. Views concerning other socio- economic impacts on the seed-to-shelves chain and the greater society generally lacked proper scientific and statistical documentation.[120] The general conclusion of the report is that the analysis of socio- economic impacts of GMO cultivation in Europe lacks the necessary objectivity.[121] While there is available analysis of the economic impacts at the farmer level, the discussion of social impacts is lacking.[122]

The Danish presidency in the Council aimed to solve the deadlock on the proposal by creating their own revised version. Since a blocking minority of Member States had until then prevented previous versions from passing, the Danish version tried to accommodate all interested parties by including a list of grounds Member States could use.[123] This is an advancement towards legal certainty when compared with the original version of the proposal by the Commission, which only contained a negative definition of the invocable grounds. In addition to grounds related to environmental policy objectives not conflicting with the evaluation of risks to health and the environment, under the Danish proposal Member States could also use 'grounds concerning socio-economic impacts that might arise from the cultivation of a GMO'.[124] It is further elaborated that the environmental grounds may only be relied on if they 'do not conflict with the assessment of risks to health and the environment which are assessed in the context of the authorization procedures'.[125] This however does raise the issue of the justification of a ban by general

120 Report from the Commission to the European Parliament and the Council on Socio-Economic Implications of GMO Cultivation on the Basis of Member States Contributions, *supra* note 119; at p. 3-5.

121 Report from the Commission to the European Parliament and the Council on Socio-Economic Implications of GMO Cultivation on the Basis of Member States Contributions, *supra* note 119; at p. 7.

122 Report from the Commission to the European Parliament and the Council on Socio-Economic Implications of GMO Cultivation on the Basis of Member States Contributions, *supra* note 119; at p. 6.

123 EurActiv.com with Reuters, "Danes Seek Compromise on GM Crops", 3 February 2012, available on the internet at http://www.euractiv.com/cap/danes-seek-compromise-gm-crops-news-510562 (last accessed on 13 June 2013).

124 Council of the European Union 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 – Revised compromise proposal in view of a Council Political Agreement (first reading). Interinstitutional File: 2010/0208 (COD) 7153/12, at p. 7 para. 12.

125 Council of the European Union Proposal for a Regulation for 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, *supra* note 124, at p. 7, para. 11.

environment policy objectives in a situation where the GMOs have already been assessed for their potential environmental risk.[126] Most likely, the environmental policy objectives may rather be relied on only for cases of limitation or prohibition of cultivation in only restricted geographical areas.

Concerning the socio-economic grounds, the four specifically mentioned by the Danish proposal are related to the difficulties of implementing coexistence measures due to geographic conditions, avoidance of GMO presence in other products, the need to protect agricultural production diversity, or the need to ensure seed and plant propagating material purity. All of these are rather concerned with more specific issues - when compared to the ones in the Commission's indicative list of grounds -, which could be evidenced by statistical and scientific data. However, the grounds of the Danish proposal also only appear to be an indicative list, as there is no suggestion of it being exhaustive.

The Danish proposal is most likely not going to be the last version of the proposal, as it failed to reach qualified majority in the Council.[127] Thus, there still is room for further improvement of the grounds. Including a list of grounds in the proposed Article 26(b) and make such a list binding could help raise legal certainty[128] while providing guidance to the Member States.[129] The improvement of the Danish proposal when compared with the original proposal from 2010, illustrates that while the issue of grounds has not been completely resolved, the creation of an indicative list and its subsequent incorporation to a certain extent into the latest proposal version indicates that the matter is being dealt with.

5.3 Compatibility with WTO Regulation

Since the European Union is a player of the global trade community, it must abide by international trade rules. Therefore, the compatibility of the proposal with WTO rules is the second main legal issue that has been frequently questioned by the Council Legal

126 Karolina Zurek, "Indicating Reasons for National GM "Opt-Outs": The Way Forward or a Dead End Street?", 2 *European Journal of Risk Regulation* (2011), pp. 241 et *sqq.*, at p. 243.

127 The reason for the failure of the Danish proposal was explained in the Press Release of the 3152nd Enviroment Council Meeting, 7478/12, at p. 11: 'Although a large number of member states could accept the Presidency proposal, it was not yet possible to reach agreement in the Council. Some member states still had concerns regarding:

• the legal compatibility of some provisions in the proposal with WTO and EU internal market rules;

• how to avoid possible overlaps and/or inconsistencies between the mandatory risk assessment at EU level and national environmental measures;

• the implementation of the Environment Council conclusions adopted on 4 December 2008.'

128 Legal certainty means that the law will have clarity, stability and intelligibility in the sense that those concerned, in our case the Member States will be able to predict with relative certainty the legal consequences of the invoked bans. See: Elina Paulino, "Beyond Predicta

129 Commission Proposal for a Regulation of the European Parliament and of the Council Amending Directive 2001/18/EC, *supra* note 8, at pp. 3-6.

Service[130] as well as Member States in the Council during the debate surrounding its adoption.[131] The proposal itself appears to be compatible with WTO rules. However, problems may arise concerning future measures that would be adopted under the future Article 26(b). The WTO Agreement on the Application of Sanitary Phytosanitary Measures (SPS) and the Agreement on Technical Barriers to Trade (TBT) are not likely to be an issue for any national measures, as the proposed Article 26b explicitly forbids the invocation of health grounds for the limitation of GMO cultivation by Member States.[132]

Rather the General Agreement on Tariffs and Trade (GATT) compatibility of the proposal could lead to possible difficulties. The recent cases of *EC-Hormones*[133] and *EC-Biotech*[134] in particular, illustrate the failure of the EU to successfully defend its protective stance towards new food technologies in front of the WTO dispute settlement body. Most of the grounds of the indicative list discussed above are unlikely to provide sufficient justification under current WTO rules. The compatibility of a newly adopted national measure limiting or prohibiting cultivation of GMOs would depend on the nature of the measure and the circumstances of the adoption.[135]

The position of the EU before the WTO is dual in its nature, as it both represents the entire Union, as well as the individual Member States. If a Member State would choose to opt out under the new Article 26b, this would lead to a shift of responsibility from the Commission to the Member States.[136]

Therefore, to conclude both in the context of EU as well as WTO law the compatibility of the proposal is largely dependent on the grounds that Member States could invoke. The proposal itself is legally compatible under EU internal market rules as long as proper justifications are provided for any future bans invoked under the proposal. However, in

130 Commission Staff Working Document on the Considerations on Legal Issues on GMO cultivation raised in the opinion of the Legal Service of the Council of the European Union of 5 November 2010, SEC(2010) 1454 final, at para. 48-65.

131 Council Press Release of the 3075th Council meeting, 7689/11, at p. 8.

132 Commission Staff Working Document – Considerations on Legal Issues, *supra* note 130, at para. 48 & 54.

133 *EC – Hormones (US)* (Article 22.6 – EC) - Decision by the Arbitrators, European Communities –Measures Concerning Meat and Meat Products (Hormones), Original Complaint by the United States –Recourse to Arbitration by the European Communities under Article22.6 of the DSU, WT/DS26/ARB, 12 July 1999, DSR1999:III, 1105.

134 *EC – Approval and Mark eting of Biotech Products*: Panel Reports, European Communities – Measures Affecting the Approval and Marketing of Biotech Products, WT/DS291/R/WT/DS292/R/WT/DS293/R, Et.1 to Et.9, and Corr.1, adopted 21November 2006, DSR2006:III-VIII, 847.

135 Commission Staff Working Document – Considerations on Legal Issues, *supra* note 130,at para. 64.

136 Weimer, What Price Flexibility, *supra* note 33, at p. 348.

order to ensure that legal certainty is provided the current proposal would need to be altered. The following section discusses our suggestions in order to achieve such greater clarity of the law.

6. Unlocking the Deadlocks?

While the Commission proposal itself has not yet provided a perfect solution to the deadlock, already the fact that a version of the proposal by the Danish presidency contained at least in its preamble an indicative list of grounds reflects on the development of the last couple of years concerning the deadlock. This is perhaps best illustrated by an example of the Commission decision on the Polish draft act on GMOs in 2008.[137] Poland at that time attempted to rely on six out of the seven socio-economic grounds of the indicative list of reasons relating to the public interest which could be invoked.[138] The Commission, however, in its decision did not even discuss the invocation of these grounds, instead only emphasizing the lack of new scientific information.[139] This is in stark contrast to the 2011 Commission document on the Indicative List of Grounds to Restrict or Prohibit GMO Cultivation, where the Commission mentions exactly those grounds that it ignored in the case of Poland three years earlier.[140]

Our own suggestion for providing a potential solution to the deadlock requires the inclusion of a non-exhaustive list of grounds in the proposed Art. 26b. The clarification of these grounds is to be supported by the creation of a committee to assess the justifications.

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137 Karolina Zurek, "Indicating Reasons for National GM "Opt-Outs": The Way Forward or a Dead End Street?", 2 *European Journal of Risk Regulation* (2011), pp. 241 *et sqq.*

138 In particular: '(1) the need to fulfil the expectations of Polish society; (2) richness of biodiversity and the need to prevent serious disturbances to the functioning of the environment; (3) the fragmented structure of Polish agriculture; (4) specific agricultural production profile with domination of conventional traditional and organic farming; (5) following from the two previous characteristics – the impossibility of elimination of a risk of cross- contamination and preventing of potential damage that could be caused as a result of crossover of transgenes into conventional crops; (6) the need to limit the cultivation of GM plants to areas that do not contain elements of value for nature conservation, and whose agrarian structure enables the safe cultivation of transgenic plants without damaging the nature and the operations of other farmers.' See in: Karolina Zurek, "Indicating Reasons for National GM "Opt-Outs": The Way Forward or a Dead End Street?", 2 *European Journal of Risk Regulation* (2011), pp. 241 *et sqq.*, at p. 244.

139 Case C-165/08, Commission of the European Communities v Republic of Poland [2009] ECR I-6843.

140 Council of the European Union Cover Note on the Complementary Considerations on Legal Issues on GMO Cultivation Raised in the Opinions of the Legal Service of the Council of the European Union of 5 November 2010 and of the Legal Service of the European Parliament of 17 November 2010, 16826/10, at pp. 2-3.

Furthermore, two possible examples for the assessment procedure to be performed by the committee are discussed.

6.1 Inclusion of Indicative List of Grounds in Art. 26b

In order to ensure legal certainty and provide some guidance to Member States for invoking a ban on societal grounds in this article we argue that an indicative list of grounds should be included in the proposed Art. 26b of Directive 2001/18/EC itself.

The indicative list proposed by the Commission is as follows:

- 'Public morals (including religious, philosophical and ethical concerns);
- Public order;
- Avoiding GMO presence in other products, i.e. contributing to:
  - Preservation of organic and conventional farming systems;
  - Avoiding the presence of GMOs in other products such as particular food products under GM-free schemes;
- Social policy objectives, e.g.:
  - Keeping certain type of rural development in given areas to maintain current levels of occupation (such as specific policy for mountain regions);
  - Town and country planning/land use;
- Cultural policy, e.g.:
  - preservation of societal traditions in terms of traditional farming methods;
  - preservation of cultural heritage linked to territorial production processes with particular characteristics;
- General environmental policy objectives, other than assessment of the adverse effects of GMOs on environment; e.g.:
  - Maintenance of certain type of natural and landscape features;
  - Maintenance of certain habitats and ecosystems (i.e. preservation of the conservation status quo);
  - Maintenance of specific ecosystem functions and services (e.g. preservation of nature-oriented regions of particular natural and recreational value to citizens).'[141]

141 Council of the European Union Cover Note on the Complementary Considerations on Legal Issues on GMO Cultivation Raised in the Opinions of the Legal Service of the Council of the European Union of 5 November 2010 and of the Legal Service of the European Parliament of 17 November 2010, 16826/10, at pp. 2-3.

While arguably an exhaustive list of grounds would provide greater legal certainty than an indicative list, as it is impossible to foresee all possible scenarios in which Member States would invoke Art. 26b in the future, a certain level of flexibility concerning the invocable justifications should be enabled. However, only providing an indicative list, while definitely being an improvement, does not provide sufficient clarity and legal certainty concerning the nature of justifications that Member States could possibly rely on. The regulatory framework should provide proper guidance for Member States in invoking the ban on societal grounds while not limiting excessively the possible invocable grounds.

The above discussed change to the proposal to amend Directive 2001/18/EC would result in an unprecedented reform of the GMO authorization framework of the European Union through the introduction of societal grounds as possibly justifications for Member States to invoke limitations or restrictions on GMO cultivation. Therefore, due to the experimental nature of such a reform, we propose to include a sunset clause in the proposed Art. 26b, with a limitation period of ten years from the moment of the coming into force of the proposed amendment.

Apart from the fact, that the list is non-exhaustive in nature, and can potentially be extended in the future, there are stil two fundamental questions to be answered. Those questions relate to the 'Who' and 'How' of the assessment, i.e. who should be in charge of this assessment, and how the grounds mentioned in the list can be operationalized in order to be compatible for assessment?

6.2 The Assessment Committee

In our opinion, the task should be delegated to a committee, established under the framework of EFSA. We argue that at the European level, EFSA's role could be redefined by the inclusion of societal concerns. This Committee could provide quality judgment concerning the sufficiency of Member States' societal assessments for legal purposes. For the sake of substantiating the societal grounds, the enhancement of a better understanding of the Member States assessment of the socio-economic impact of GMO cultivation could also be a task of the committee. The creation of such a committee is arguably necessary as without it the functioning of the proposal could be prejudiced. Currently, there is no such entity that could provide sufficient guidelines concerning the invocation of societal grounds. Such an EFSA committee could provide guidelines concerning the acceptability of societal grounds as right now there is no such committee providing those guidelines. The Member States competent authority would forward their societal assessment on GMOs to that committee. Consequently, EFSA's committee would write a report on the basis of the individual Member States' societal reports and hand them to the Commission. The Commission would then regard the individual Member States' concerns.

6.3 Possible Assessment Practices

After having clarified the issue of the entity responsible for the task of the assessment of invocable grounds, the next question to elaborate on, concerns the operationalization of the grounds in order to accomplish the assessment. Two examples are provided that could enhance the process of assessment, which are firstly based on a report of the European Commission and the Parliament, and secondly on the reporting practice of the Dutch *Commissie Genetische Modificatie* (COGEM).

A joined report from the European Commission and the Parliament from December 2009 indicates that "the understanding of the meaning and scope of the socio-economic dimension of GMO cultivation varies widely among Member States and the stakeholders".[142] Furthermore, the socio- economic implications "are often not analyzed in an objective manner".[143] Therefore, it is necessary to establish systematic analytical guidelines, which clearly instruct on how to conduct the assessment and, even more important, which aspects shall be part of this assessment.

In recent decades, the importance of ´social impact assessment´ (SIA) has increased. `Social impacts` thereby refer to the consequences which affect the population due to a public or private action. This can relate to lifestyles, work, social relations, but also norms, values and belief systems.[144] The SIA then can be defined as the attempt of an *a priori* examination of an event or policy action. Thus, attempting to give a prognosis on social implications.[145]

The EU Impact Assessment Guidelines list thirty-five dimensions, which are related to Economics, Social Affairs and Environmental and Health Concerns. As the amendment proposal excludes grounds on environment and health, these dimensions cannot be part of a SIA. We identified ten dimensions in total (Table 1), which could be related to the cultivation of GMOs and grounds for a GMO ban.

142 Commission Report to the European Parliament and the Council on Socio-Economic Implications of GMO Cultivation on the Basis of Member States Contributions, as Requested by the Conclusions of the Environment Council of December 2008, COM(2011) final, at p. 3.

143 Commission Report on Socio-Economic Implications, *supra* note 142.

144 Commission Impact Assessment Guidelines, SEC(2009) 92, at p. 1.

145 COM Impact Assessment, *supra* note 144.

Internal Market	Competitiveness, trade	Specific regions/ sectors	Employment/Labour market	Innovation and Researchs
Consumer choice	Global competitive position of EU	Effect on certain sectors	Job creation	Stimulate/hinder research
Higher prices	Trade barriers	Effect on certain regions	Loss of jobs	Technological development
Creation of barriers	Crossborder investment flows	Disproportionally affected region/MS	Particular negative consequences	Property rights
Anti-competitive behaviour			Age groups	Academic/Industrial research
Market segmentation			Demand for labour	Productivity/ Efficiency
			Functioning of labour market	
Macroeconomics	**Culture**	**Admin. burdens on businesses**	**Consumers**	**Third countries effects**
Economic growth	Impact on cultural heritage	Obligations placed on businesses	Effect on prices	Trade/Investment flows
Conditions for investment	Cultural diversity	Impact on SMEs in particular	Benefit from internal market	Specific groups
Proper functioning of markets	Access to cultural resources	Disproportionally affected region/MS	Availability/Quality of goods	International standards, Common regulatory approaches
Macro-economic stabilization			Consumer protection	Effect on countries with PTA
			Financial situation of individuals	Effect on developing countries
				Adjustment costs on developing countries
				Effects on goods and services by developing countries

One of the most important aspects is the compatibility of unilateral GMO bans on the Internal Market. As stated in the previous section, it is important that Member States,

wishing to ban a GMO from cultivation on their territory, is in line with Article 26 TFEU, thus, the functioning of the Internal Market must not be distorted.

More difficult to assess is the possible negative effect on EU competitiveness as a whole, if a Member State or a group of Member States is willing to ban a GMO from cultivation. As the case of Monsanto, which plans to leave the European market,[146] indicates, there can be adverse effects on the European Union`s competitive position. It is not unlikely that more GM companies will follow Monsanto, leaving the EU as the only continent without GM cultivation. Investments into research and plants then also might be restrained. This dimension is closely linked with Macroeconomics and Employment.

The employment dimension relates to the creation or loss of jobs due to a certain policy measure. Applied to the case of GMOs, an SIA has to measure in how far jobs and employment opportunities are created or destroyed by GMO cultivation in a certain region or country. It might be the case that GMOs destroy traditional economic structures, or make it even impossible to grow non-GMO seeds, since it is practically impossible to prevent GM pollen to spread to non-GM plants. This is particularly troublesome with regard to organic farming, as the case of Austria demonstrates.

The regional dimension also takes into account that different European regions would be affected differently by GMO cultivation, due to geographical, agricultural and social factors. This aspect is decisive in the local populations' acceptance of GMO cultivation. The SIA should also take into account specific regional economic sectors, which can be affected. A further aspect is the cross-border effect of GMO cultivation in frontier areas, when a pro-GM country shares a border with a GM-free Member State.

In terms of innovation and research, it has to be assessed, whether a ban of GMOs might have adverse effects on terms of research in the EU and certain Member States. Many GM companies are research-intensive units. Again, the question has to be answered, whether bans might lead to an exodus of exactly those kinds of companies, which play an important role in the so-called future markets, such as bio-technology. Innovation is an important economic growth factor. This also relates to other objective the EU aims to pursue, such as the science and research strategy.[147] In this respect, it is evenly important to take the broader macro-economic picture into account. Unilateral bans might worsen the conditions for investments and distort the functioning of markets, but also the

146 Zeit Online, "Monsanto stellt Genforschung in Europa ein", 31 May 2013, available on the Internet at: http://www.zeit.de/wissen/umwelt/2013-05/monsanto-gentechnik-saatgut.

147 Commission Communication on Europe 2020: A Strategy for Smart, Sustainable and Inc lusive Growth, COM(2010)2020, at p. 8.

prospects of economic growth could be negatively affected, when certain industries are practically excluded from a countries´ market.

The cultural dimension lacks clarity; however, it is conceivable that certain aspects of traditional agriculture are regarded as cultural heritage. It then has to be evaluated, in how far this is affected by GMO cultivation. Nevertheless, this remains an ambiguous issue. Another important aspect is the burden for companies, when cultivation is only possible in certain Member States. Due to differences in climate and landscape, not every country is eligible for cultivation of all seeds, so a GM company might not be able to shift cultivation to a pro-GM Member State. On the other hand, structural changes in European agriculture might include the growing dependence on large seed enterprises, such as Monsanto or Bayer.

Consumer protection is a decisive issue in food policy. In relation to GMOs this can include the availability of certain goods, as well as the effect on prices, when the market is dominated by certain companies or products. On the other hand, consumers should benefit from the internal market, thus, they should have a choice in deciding whether to buy and consume GM products, or not. This requires product safety, as well as quality of goods.

Finally, it should be assessed in which ways unilateral import bans might affect third countries. This concerns investment and trade flows, but also the adherence of international standards. With regard to GMOs third countries might be affected as being the new target countries for GM companies, as the cultivation in Europe is hindered. This could lead to a displacement of traditional agriculture in developing countries and an alteration of the national economic structure. Social problems in developing countries might be aggravated or social tensions evoked.

Another example for the possible assessment of grounds can be based upon the reporting practice of COGEM in the Netherlands. As an advisory body COGEM *inter alia* informs the Dutch government of "ethical and societal issues linked to genetic modification."[148] In its topic reports "COGEM has analysed the GMO debate, reported on [the] societal consequences of new technological developments, and inadequacies in the GMO regulations".[149] Such a COGEM "topic report" on societal concerns employs social sciences to analyze societal or ethical concerns. These include socio-economic, cultural and ethical implications of GMOs.

In summary, it can be stated that the amendment proposal is a significant progress. The creation of a separate unit assessing societal implication of GMOs seems necessary as without it, the proposal could not function. The proposal only contains a non-exhaustive list, which does

148 COGEM, "Home page", available on the Internet at: http://www.cogem.net/index.cfm/en/cogem/.

149 COGEM, "Topic Reports", available on the Internet at: http://www.cogem.net/index.cfm/en/activities/topic -reports/.

not provide sufficient clarity as to what exactly could be invoked. Thus, evoking the safeguard clause on socio-economic, cultural or ethical reasons by a Member State would constitute an act of national concern, if based on justifiable grounds, and no longer be a concern for the entire internal market. This would be a step to de-harmonize a policy area, GMO cultivation in this respect. Although, such a reform would be a novelty in the history of European integration, such a regulatory framework would acknowledge national diversity across the EU. However, it is important to operationalize the indicative grounds towards clear assessment variables, on which basis it is possible to evaluate the Member States´ bans in a more systematic manner. The assessment should be performed by a committee, which is incorporated under EFSA`s roof, but which is separated from the scientific assessment. Furthermore, we propose to introduce the changes for an experimental period of ten years, in which the new regime can be evaluated. Thus, we argue that the proposed changes discussed above do have the potential to provide a solution to the one aspect of the deadlock. Specifically, through the inclusion of grounds in Art.26b and the creation of an assessment agency, Member States could receive sufficient guidance for the invocation of non-scientific grounds. Therefore, the deadlock concerning the frequent reliance of Member States on the safeguard clause with claims of new scientific evidence could be if not altogether avoided, but at least limited.

7. Accommodating Diversity – The Broader Picture

Put in broader perspective, the proposed amendment described and justified in the last section does not present a certain and final solution to both. The Hydra-like nature of GMO authorization makes reforming very difficult and complex as various stakeholders mean various opinions to incorporate; furthermore, the inherent problems with science as an arbiter remain, similar to the immortal head of the Hydra. Nevertheless, the direct inclusion of societal concerns into the debate on GMO cultivation bans and the use of social sciences to measure and assess these concerns is an important step forward towards a risk regulation process that is closer to reality.[150] The increased demand for enclosing

150 Calls for such an inclusion *inter alia* by: Zurek, K. (2013), Regulating Food Trade in the Enlarged European Union, in Marjolein B.A. van Asselt, Esther Versluis & Ellen Vos (eds.), *Balancing between trade and risk: Integrating legal and social science perspectives,* (London, UK: Routledge, 2013), pp.15 et *sqq*.; Ariane Königa, Harry A. Kuiperc, Hans J.P. Marvinc, et al., "The SAFE FOODS framework for improved risk analysis of foods", 21, *Food Control*, (2010), pp.1566 et *sqq*.; Marion Dreyer, Ortwin Renn, Shannon Cope, & Lynn J, Frewer, "Including social impact assessment in food safety governance", 21, *Food Control*, 2010, 1620 et *sqq*.; Vessela Hristova, "Accommodating National Diversity in GMO Regulation" in Marjolein B.A. van Asselt, Esther Versluis & Ellen Vos (eds.), *Balancing between trade and risk : Integrating legal and social science perspectives* , (London, UK: Routledge, 2013), pp.107 et *sqq*.; Mihail Kritikos, "Traditional risk analysis and releases of GMOs into the European Union: space for non- scientific factors?", 34, *European Law Review*, (2009), pp.405 et *sqq*.

non-scientific grounds in the process of banning GMO cultivation by Member States and societal stakeholders (as shown by events such as global protests against Monsanto and the media coverage of these)[151] corroborates that the amendment as such is important; the proposed changes hopefully facilitate to agree upon it.

Especially after the EU enlargements in 2004 and 2007, the EU comprises Member States with various different backgrounds and social structures. As argued above, a ban on cultivation also has repercussions on the internal market and trade concerns as GM seeds are an unpopular product if one cannot use them. Concerning the internal market, the "heterogeneity implies slightly different needs and is more difficult to manage",[152] being one more reason for Zurek, a legal scholar analysing the regulatory regime of EU food trade, to include socio-economic grounds and consequently increase embeddedness of the decision-making process.[153]

Hristova, a political scientist studying to what extent GMO regulation incorporates Member States' opinions, describes two ways of accommodating this present diversity: deliberation and differentiation. While it is attempted to consider scientific and non-scientific concerns of all stakeholders in the decision-making process through deliberation, differentiation steps in after the authorization of a certain GMO has taken place and allows Member States to abstain from the authorization.[154] With the amendment proposal of the Commission, the latter seems to favour reforms in the direction of differentiation since Member States would be able to ban GMOs *post*-authorization. As our proposal is based on this approach, we deviate from Hristova's analysis. In contrast to her view, the de-

151 NOS, "Wereldwijd protest tegen Monsanto", 25 May 2012, available on the Internet at:http://nos.nl/video/510739-wereldwijd- protest-tegen-monsanto.html (last accessed 30 May 2013); Hunffingtonpost, "March Against Monsanto' Protesters Rally Against U.S. Seed Giant And GMO Products", 25 May 2013, available on the Internet at: http://www.huffingtonpost.com/2013/05/25/march-against-monsanto-gmo-protest_n_3336627.html (last accessed on 30 May 2013); NY Daily News, "Monsanto protesters across globe rally against firm's genetically modified food products", 25 May 2013, available on the Internet at: http://www.nydailynews.com/news/national/monsanto-protesters-globe-rally-firm-genetically-modified-food-products-article-1.1355457 (last accessed on 30 May 2013); Aljazeera, "Worldwide protests held against Monsanto", 26 May 2013, available on the Internet at http://www.aljazeera.com/news/americas/2013/05/201352519535223643 9.html (last accessed on 30 May 2013); Leonie Sontheimer, "Märsche mahnen Monsanto", Die Tageszeitung, 25 May 2013, available on the Internet at http://www.taz.de/!116800/ (last accessed on 6 June 2013).

152 Zurek, Regulating Food Trade in the Enlarged European Union, *supra* note 31, at p. 22.

153 It is also interesting to note that Zurek foresaw the second deadlock in a way: "There is a risk, however, that in order to get away from the transnational conflict, the EU will allow for new internal conflicts and internal EU regulatory fragmentation", ibid.

154 Hristova, "Between Politics and Science. Accommodating National Diversity in GMO Regulation", *supra* note 30.

harmonisation and distribution of power back to the national level that might follow the proposal is not perceived as a negative consequence for the EU and the internal market.[155]

Risk regulation and possible cultivation bans are a trade issue also prevalent in the WTO context. In line with the argumentation of the legal scholar Weimer, current legal frameworks at WTO level forbid unnecessary trade restrictions, but also are already "recognised for being more generous in recognising the importance of certain values when weighed against the negative effects on trade".[156] Additionally, inside the US internal market there already is the model example of the situation in which possible bans at state level are allowed, but that social concern at the higher level does not allow for a national ban. Although this is the case for the chemical Bisphenol A, the issue at stake still is risk regulation in the situation of uncertainty.[157] In reference to the widespread concern in some Member States that cultivation bans might be a hindrance to the internal market, it might be more feasible to generally argue for a cal for 'free movement of *most* goods' in some sectors instead of the so far predominant notion of free movement of goods. This sector-by-sector approach would furthermore contrast a too strict and inflexible risk regulation, which in turn probably leads to a growing discontent in society.[158] All this also relates back to the aim of the differentiation method by Hristova to accommodate diversity and different concerns of stakeholders.

The coexistence of natural and social sciences in this article's proposal also aims to shed more light into the bias of science in general. Similar to what was argued above, Weimer stresses that the nature of science is socially constructed and influences the evaluations excessively.[159] Social science studies are also biased due to the importance of definitions of social impact and acceptable thresholds.[160] On another note, risk regulation faces the struggle of political influences.

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155 "Hristova warns that accommodating diversity will affect the constitutional characteristics of the EU, as it implies redistributing political authority", Van Asselt, M.B.A., Fox, T., Versluis, E., & Vos, E. Regulating Innovation, Trade and Uncertain Risks. In Marjolein B.A. Van Asselt, Esther Versluis & Ellen Vos (eds.), *Balancing between trade and risk: Integrating legal and social science perspectives*, (London, UK: Routledge, 2013), pp.15 et *sqq*, at p. 258.

156 Weimer, "EU Risk Governance of 'Cloned Food'", *supra* note 33, at p.47

157 Fox, T., Versluis, E., & van Asselt, M.B.A. (2013), Regulating the Use of Bisphenol A in Baby and Children's Products in the European Union, p. 159.

158 Zurek, Regulating Food Trade in the Enlarged European Union, *supra* note 31, at p. 22 & p, 28.

159 Weimer, "EU Risk Governance of 'Cloned Food'", *supra* note 33, p. 49

160 Marion Dreyer, Ortwin Renn, Shannon Cope, & Lynn J, Frewer, "Including social impact assessment in food safety governance", 21, Food Control, 2010, 1620 et *sqq*, at p. 1623.

This is called de-politicisation,

> a politicisation of the scientific executive function, which might (...) lead to obscure and insensitive decision making at the level of the simple application of science to complex social relations, and one which might (...) deny its own normative under-pinnings".[161]

We think that the combination of both kinds of sciences is needed so that a) these biases become clearly acknowledged and communicated inside and outside of EFSA, also leading to more uncertainty tolerance and b) a justifiable and objective risk assessment is ensured. Without science, undesirable arbitrary risk regulation would be more probable as politics might be even more influential than it is now.[162] Natural and social sciences thus are essential for improving the risk regulation process in the direction of more embeddedness and against an infeasible one-size- fits-all approach;[163] in the attempt to come closer to a solution to the deadlock, it is therefore suggested that the diverse concerns are accommodated by differentiation and the inclusion of social sciences next to natural sciences.

8. Conclusion

In this article, we aim to analyse to what extent the two deadlocks in the authorization of GMO cultivation can be unlocked. The GMO authorization process is an allegoric Hydra as complex and various issues lead to continuous debates and blocking minorities in the decision-making procedure. Several current events present the GMO authorization as a hot topic: first, Monsanto declared to left the EU internal market due to the persistent banning of MON810 in some Member States; second, global protests against the same company have spread awareness of the topic and have shown the widespread concern of the public, and third, the Commission has announced to revive talks on a draft amendment of Directive 2001/18/EC.

This latter draft legislation aimed at solving the first deadlock, being the continuous and adamant invocation of the safeguard clause by Member States such as Austria, on the one hand, and the persistence on the illegality of those bans by EFSA and the Commission, on the other hand. The fact that not only Austria, but several others also banned MON810

161 Everson & Vos, The scientification of politics and the politicisation of science, *supra* note 17, at p.6.

162 On the inherent political nature of risk assessment, see for example pp. 266-271.

163 Miriam Hartlapp, Gerda Falkner, Simone Leiber, Olive Treib, *Complying with Europe: EU Harmonisation and Soft Law in the Member States,* (Cambridge: Cambridge University Press, 2005).

shows that the Member States do not trust EFSA's risk assessment entirely based on natural sciences, that GMOs are safe. Main reasons for this mistrust is scientific uncertainty and the existence of scientific studies differing in their evaluations of risks. As different science and technology scholars argue, science is no value-free arbiter as different methods and research questions result in different outcomes. Another problem described in our section on science is that risk managers at the EU level mainly argue in line with risk assessment without reflecting on scientific bias. Furthermore, non-risk grounds such as moral, ethical or socio-economic related ones are major reasons for some of the bans and especially for the high sensitivity of the debate. These several problems faced in the GMO authorization process can allegorically be seen as the numerous heads of the hydra. Whereas in mythology Herakles managed to defeat the Hydra after several attempts, this is still an ongoing battle at the EU level as the Commission, sometimes together and sometimes against the Member States, tries to solve all the problems.

Focusing on the problem with risk issues, the Member States urged the Commission to propose the amendment which would enable bans based on non-risk grounds. However, a minority of Member States blocked the decision-making in the Council by reasoning with two substantive legal objections. First, it is assumed that the bans would hinder the internal market under Article 34 and needed to be justified under Article 36 of the TFEU. Second, opposing Member States argued with non-existent WTO compatibility. In our analysis, it is however made clear that both concerns are not appropriate as long as proper justifications for the bans are given. Based on both analyses, we propose a) an exhaustive list of grounds in order to safeguard legal certainty, b) the inclusion of a social impact assessment to guarantee non-arbitrary bans on non- risk grounds, and c) the establishment of an assessment committee as part of EFSA. The particular task of this committee is to ensure the evaluation of the assessments based on social sciences. As we are aware of the struggle to reform this complex policy domain, we argue for a sunset clause in the amendment to allow for continuous improvement of the regulatory procedure.

It also needs to be recognized that this proposal is a first step forward to accommodating diversity by the method of differentiation. Acknowledging the limits of science and expanding its scope at the same time, we hope that if results and issues of both natural and social sciences are discussed, the problems of scientific bias and uncertainty can be taken into account. It is interesting to see how the situation of the two deadlocks develops in the future. More research should be conducted to investigate on how social sciences can be included in the future authorization process of GMOs in the context of EU risk regulation and the already established agencies. Moreover, it is worth observing the contemporary tensions surrounding the GMO debate such as Monsanto leaving the European market, two-thirds of the European public opposing GMOs and whether new problems arise.

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Academic Year 2013–2014

Politicisation of Science in the Process of Dealing with Manufactured Risk

An Interdisciplinary Case Study

Yann Finger, Leïla Jebri, Frieder Kühne, Lena Scheffel, Matthias Schnippe

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1. Introduction

> The irony of [manufactured] risk here is that rationality, that is, the experience of the past, encourages anticipation of the wrong kind of risk, the one we believe we can calculate and control, whereas the disaster arises from what we do not know and cannot calculate.
>
> U. Beck, 2006, p. 330

A key feature of modern society is the emergence of new characteristics of risks, which have been conceptualized by U. Beck as 'manufactured risk'.[1] Whereas in the past, risks principally consisted of natural hazards, which were limited in both time and space, manufactured risks are man-made, have a global effect, are potentially catastrophic, and can only be assessed speculatively. The global dimension of these risks has rendered apparent the latent divergence in the conceptions of risks that exist among different nations and regulatory regimes, thus resulting in tensions at and between national, regional, and international levels.

One of the entities where these conflicts are most visible is the World Trade Organisation's (WTO) dispute settlement body, which has recently been faced with several cases relating to manufactured risk.[2] In these situations, and partially due to the WTO's need to legitimize its going beyond national sovereignty, science has gained paramount importance in providing for a neutral and objective international normative yardstick for decision-making.[3] Indeed, such function of science is exemplified in the *WTO Agreement on the Application of Sanitary and Phytosanitary Measures* (SPS Agreement), which indicates that, in order to leave to Member States their discretion to set the levels of protection, the WTO only 'disciplines' the existing risk assessments, thus ensuring that the risk regulations are appropriately based on science. In this respect, a clear-cut distinction

1 Ulrich Beck, *Risk Society: Towards a New Modernity* (SAGE Publications 1992).

2 WTO, *European Communities - Measures Concerning Meat and Meat Products (Hormones)* (13 February 1998) WT/DS26/AB/R, WT/DS48/AB/R; WTO, *European Communities - Measures Affecting the Approval and Mark eting of Biotech Products (EC-Biotech)* (21 November 2006) WT/DS291, 292, 293/R.

3 Jacqueline Peel, 'Risk Regulation Under the WTO SPS Agreement: Science as an International Normative Yardstick' (2004) Jean Monnet Working Paper 02/04 http://www.jeanmonnetprogram.org/archive/papers/04/040201.pdf accessed 20 May 2014.

is made between risk assessment, which provides for objectivity and authority, and risk management, which is expected to appropriately respond with policy decisions.[4]

The undisputed reliance on science, in case of manufactured risk, is problematic concerning two central aspects. Firstly, 'risk' is stil mainly conceptualised according to the traditional theory, which states that risk can be managed by rationally evaluating the probability of its occurrence and measuring it against the extent of the harm that might be caused by a disaster.[5] However, due to the speculative characteristic of manufactured risk, no historical data exist regarding the probability, the form, or even the existence of these risks. As these aspects can only be evaluated retrospectively, a mere positivistic[6] description of what manufactured risk consists of is drastically jeopardised. Secondly, the way science is being used as an 'internationallyardstick' fails to acknowledge and problematize the ways science may be politicised, thus potentially leading to a misuse of scientific knowledge when dealing with manufactured risk.

Consequently, this paper will investigate some potential effects of the current use of science with regard to manufactured risk. To start with, the WTO's approach towards science and its limiting definition of risk, appears not only incomplete vis-à-vis emerging forms of risk, but also ignores the practical inability of science to be used as a decisive tool in dispute settlement. Subsequently, the demeanour of displaying scientific knowledge as complete, unequivocal, and authoritative as well as disregarding the existence of various forms of uncertainty results in a *de facto* impediment of Member States' freedom to "determine their own appropriate level of sanitary protection".[7]

Therefore, this paper will empirically analyse how scientific knowledge is being politicised in the process of dealing with manufactured risks. For this purpose, the interdisciplinary analysis of a case concerning the selected genetically modified organism

4 This is particularly visible in the objective of the SPS Agreement as interpreted by the at the WTO website "[...] the SPS Agreement allows countries to set their own food safety and animal and plant health standards. At the same time, however, the SPS Agreement requires that such regulations be based on science [...]" http://www.wto.org/english/tratop_e/sps_e/sps_agreement_cbt_e/c1s1p1_e.htm accessed 14 May 2014.

5 Marjolein van Asselt, Ellen Vos, Bram Rooijackers, 'Science, knowledge and uncertainty in EU risk regulation' in Michelle Everson and Ellen Vos (eds), *Uncertain risks regulated* (Taylor & Francis 2009).

6 For sake of clarity, all further use of the term 'positive' or 'positively' will be in accordance with the meaning of "Consisting in or characterized by the presence rather than the absence of distinguishing features." Oxford Dictionaries <http://www.oxforddictionaries.com/definition/english/positive> accessed 13 June 2014.

7 Panel Report, *Hormones* (n2) 172.

(GMO), Bt-176,[8] will be presented. This specific GMO was banned in Germany, Austria, and Luxembourg, accepted by the European Communities (EC, now: European Union),[9] and assessed in the WTO Dispute Settlement on the *Measures Affecting the Approval and Marketing of Biotech Products (EC-Biotech)*.[10]

On this basis, the authors will, in the first part, propose a conceptual framework significant in evaluating how the relevant authorities at the national, EU, and WTO levels approach scientific knowledge when dealing with manufactured risks. In the following section, the paper will analyse the various facets on which the scientific evidence presented by Member States and the EC agencies conflict. Finally, the way the WTO Panel 'disciplined' the risk assessments, according to applicable law, will be investigated. Based on the analysis of the *EC- Biotech* case, diverging manners by which science is being politicised will be identified. In particular, the paper will investigate how different types of uncertainty are being ignored or disregarded, thus ultimately leading to the limitation of available evidence on which Member States can base their safeguard measures.

In conclusion, the argument substantiated in this paper is that, due to the characteristics of manufactured risk and the inherent politicisation of science, under no circumstances should science be used as the most important normative yardstick in the WTO decision-making process. Additionally, this paper claims that in order to appropriately deal with manufactured risk and its speculative characteristic, scientific risk assessment should not only attempt to positively assess the risk, but as well attribute a major importance to all identified forms of uncertainty.

2. Conceptual Framework

2.1 Manufactured Risk

It is useful to recal that 'risk' is not a natural category, but a concept that has been contingently defined to render a given reality intelligible. In this context, the definition of risk, and what it refers to, varies greatly. As the literature on risk perception demonstrates, the term 'risk' is composed by numerous factors that complexly interact and differ from

8 ID-Number: SYN-EV176-9 < http://www.gmo-compass.org/eng/gmo/db/51.docu.html> accessed 20 May 2014.

9 In the following of the paper, the authors will use the term European Communities (EC) having regard to the historical context which took place before entry into force of the Lisbon Treaty.

10 Panel Report, *EC-Biotech* (n2).

one culture to another.[11] Consequently, the way 'risk' is defined, sets the relevant criteria in the governance of risk, thus having great repercussions on the perceptions of risk as well as on the manner it is being dealt with.

Historically, the concept of risk seems to have made its first appearance, in the western world, with reference to the danger of sailing in uncharted waters and the cost of potential loss of shipments.[12] However, it is only in the 19th century, that the term 'risk' became dominant over the notion of 'hazard', and its usage in the English literature has boomed since the 1960s.

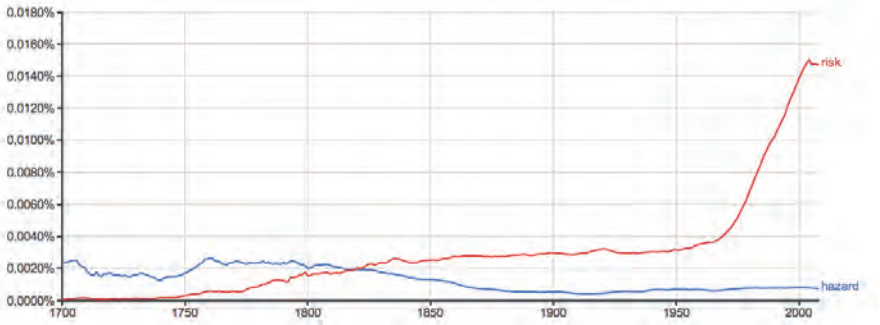

Figure 1 Risk & Hazard (source: Google Ngram[13])

The German sociologist U. Beck, in his influential book *Risk Society: Towards a New Modernity*, explained the change that took place in the 19th century by referring to the enlightenment and the industrial revolution.[14] In that time, science progressively gained a central role in western societies and, with the development of statistics, was able to introduce a rational definition of hazard, stripping away its randomness and relation to fate. In this context, the new usage of the term 'risk', referred to the quantifiable identification of the probability of a harmful event to occur. Such calculative interpretation of risk was accordingly conducted through probabilities, mathematic principles, and predominantly based on statistical data within the economic paradigm.[15] This way of

11 sk: A -*Trust*

12 Asselt, 'Perspectives on Uncertainty and Risk: The PRIMA approach to decision-support' (PhD thesis, Maastricht University 2000).

13 Results based on keyword search for 'risk' and 'hazard' using Google Ngram viewer.

14 Beck (n1).

15 Gabe Mythen, *Ulrich Beck : A Critical Introduction to the Risk Society* (Pluto Press 2004).

treating risk appeared to be greatly useful when dealing with risk that could be statistically documented and for which insurances could compensate the losses.

However, in the second part of the 20th century, and consistently with the increased use of the term 'risk' (*cf.* figure 1), Beck identified an emerging kind of risk – *viz*. 'manufactured risk'.[16] This type of risk arises from unforeseen implications of the growing role of technology in society and of the human design on the natural world. In contrast to natural hazards, manufactured risk are man-made, illimitable in time and space, potentially catastrophic,[17] and speculative.[18] By speculative, Giddens refers to the fact that, despite extensive scientific knowledge, uncertainties might persist with regard to whether these risks actually exist, as well as the exact form they could take or the way to calculate them.[19] In this regard, scientific expertise holds an unsettled role. On the one hand, many manufactured risks transcend our sensory capacities and, as such, require the help of science to render such risks manageable. On the other hand, the uncertainties caused by the futurity of the risk and its incalculability cannot be simply dispelled by yet further scientific advance.[20]

The authors argue that, the concept of manufactured risk is useful to grasp some of the empirical characteristics of risk relating to genetically modified organisms, and improve the quality of regulatory decisions on such kind of risk.[21] Firstly, GMOs are the results of scientific and technological development, and the willingness to impose the human design upon nature.[22] Secondly, once released in nature they become impossible

16 While Beck argued for an ontological distinction between manufactured risk and natural hazard, the authors do not believe in such clear-cut division. Instead 'manufactured risk' is used as a useful concept to highlight the complexity and diverging characteristics of modern risks.

17 Corinne Wales and Gabe Mythen, 'Risky Discourses: The Politics of GM Foods' (2010) 11 Environmental Politics 121, 124.

18 Giddens (n12).

19 ibid.

20 van Asselt, Vos and Rooijackers (n5).

21 Certain authors such as Andreas Klinke & Ortwin Renn propose up to seven different types of risk with specific policy advice on how to deal with each of them. However, in the scope of this paper, the aim is not to render the category of 'manufactured risk' a recognised tool for policy making but merely to point at certain aspect of modern risk, which are usually overlooked in the process of risk regulation. For this purpose we find the characteristics of 'manufactured risk' more extensive than the ones presented by Klinke & Renn. See: Andreas Klinke and Ortwin Renn, 'A New Approach to Risk Evaluation and Management: Risk-Based, Precaution-Based, and Discourse-Based Strategies' (2002) 22 Risk Analysis 1071.

22 Sheila Jasanoff, *Designs on Nature: Science and Democracy in Europe and the United States* (Princeton University Press 2005).

to be retrieved to the laboratory, as the manufactured risk does not disappear after the harvest. Thirdly, GMOs are traded and cultivated worldwide, thus, in case harmful effects were to be detected, the extent of the damage would be global and unlimited in time. Finally, the risk related to GMOs remains speculative and hence, the ability of science and technology to deal with them is severely impeded. Consequently, the following parts of the paper will be concerned with framing and identifying the issues arising from current perceptions of risk when dealing with manufactured risk.

2.2 Precaution and Types of Uncertainty

The emergence of the widely debated precautionary principle, in the last quarter of the 20th century in Europe, can be indirectly considered as an attempt to respond to manufactured risks. Indeed, in the light of their speculative nature, the lack of historical experience and of consensus on the relevant criteria to be assessed, the uncertainties surrounding the potential risk need to be addressed.[23] In this regard, it does not come as a surprise that the current literature on risk governance and the precautionary principle refers to 'uncertainty' as a central aspect for the establishment of precautionary measures.[24] However, the notion of 'uncertainty' is a broad concept that contains diverse meanings. In this respect, a meta-analysis of the various uses of the term 'uncertainty' al ows the authors to distinguish four types of uncertainty.

The first, and most criticized, type of uncertainty consists of what has been referred to as the Knightian conceptualization of uncertainty.[25] Knight was an economist that perceived uncertainty as being clearly distinguishable from risk. From this perspective, uncertainty only amounts to a temporary lack of data that disables risk to be assessed. Once the scientific evidence is sufficient, the uncertainty is resolved. Consequently, precautionary measures can only be taken if it is proven that the current body of scientific knowledge clearly lacks some information. In such case, precautionary measures apply for

23 Additionally, as great amount of the social science literature on the subject pointed out, the process of risk assessment should include social scientists and even the participation of the citizens. Indeed, since 'risk' is not a natural category but a social one, it is of prime relevance that all the sta keholders can adequately be represented in the definition of 'risk'. See for example: Brian Wynne, *Rationality and ritual: Participation and exclusion in nuclear decision -making* (Routledge 2013).

24 See: Everson and Vos (n5); Sylvia Noble Tesh, *Uncertain Hazards: Environmental Activists and Scientific Proof* (Cornell University Press 2001); Elizabeth C Fisher, Judith S Jones and René von Schomberg, *Implementing the Precautionary Principle: Perspectives and Prospects* (Edward Elgar Publishing 2006).

25 van Asselt, Vos and Rooijackers (n5); Ellen Vos and Marjolein van Asselt, 'The Precautionary Principle and the Uncertainty Paradox' (2006) 9 Journal of Risk Research 313.

a restricted period during which additional scientific evidence should be collected and the uncertainty cleared up.

The second type of uncertainty is derived from the Science, Technology & Society (STS) literature.[26] In this context, uncertainty is, *inter alia*, perceived as a lack of consensus among the scientific community. In reality, scientific practice bases itself on collected data, among which specific information will be selected in order to develop, through different strategies and methodologies, new theories. This complex process generally results in disagreement within the scientific community as to which data are relevant and how should they be interpreted. These disputes may persevere but wil typically reach a consensus (also referred as 'closure'). Such consensus is generally not the result of the gathering of new scientific evidence, but of a complex process in which relevant actors, come to interactively construct common definitions and meanings.

The third type of uncertainty, 'system complexity', is a general tenet of ecological science,[27] and is particularly problematized by C. Perrow in *Normal Accidents*.[28] In essence, Perrow argues that, in systems which are both 'complex' and 'tightly' coupled, inherent and irreducible risk will persist. Indeed, the complexity of a system implies that, due to the multiplicity and the entanglement of the interactions between components, uncertainty will always remain. Nuclear energy or DNA changes are examples of such tight and complex systems – in such cases, the uncertainty is inherent to the physical properties of the system.[29] Moreover, ecological science advocates for a perspective recognising the complexity of the interactions between the components, whereas mainstream laboratory science, which attempts to identify the causal relation between components, tends to decontextualize them from the environment they would naturally evolve in.[30]

The fourth, and final, kind of uncertainty is tightly related to the second one, but instead focuses on uncertainty as an inherent and irreducible part of scientific practice. Due to various aspects intrinsic to the practice of science, such as the clash of scientific

26 Bruno Latour, *Politics of Nature*: *How to Bring the Sciences into Democracy* (Harvard University Press 2004); Lawrence Busch, Robin Grove-White, Sheila Jasanoff and others, *Amicus Curiae Brief. Submitted to the Dispute Settlement Panel of the World Trade Organization in the Case of EC Measures Affecting the Approval and Mark eting of Bio -tech Products* (2004). <http://are.berkeley.edu/courses/EEP131/fall2007/WinikoffGMO.pdf> accessed 14 May 2014.

27 Hugh Lacey, *Values and Objectivity in Science: The Current Controversy about Transgenic Crops* (Lexington Books 2005).

28 Charles Perrow, *Normal Accidents: Living with High Risk Technologies* (Princeton University Press 2011).

29 ibid.

30 Lacey (n27).

paradigms, and the fact that scientific knowledge is often noncumulative, uncertainty, with higher or lesser degree, cannot be eradicated.[31] However, such uncertainty is not necessarily negative as, for instance, various scientific paradigms may represent an increased array of perspectives and assist decision makers. On the other hand, the existence of this type of uncertainty undermines the possibility for the body of scientific knowledge to speak with one authoritative voice.

It is relevant to emphasise that all these types of uncertainty are not mutually exclusive. On the contrary, the authors believe that the assessment of manufactured risk should explicitly address an array of different types of uncertainty. Additionally, a distinction between, on the one hand, the kinds of uncertainty that can be dealt with (type one and two), and the ones that are irreducible and inherent (three and four), is observable. Lastly, one can notice that some types of uncertainty account for ontological characteristics while others are related to the practice of science itself (i.e. to epistemological characteristics). In general, epistemological types of uncertainty should not necessarily be equated with risk. For instance, while uncertainty as conflicting scientific perspectives does not allow scientific knowledge to authoritatively speak with one voice, it remains a beneficial kind of uncertainty as it presents differing angles on a risk.

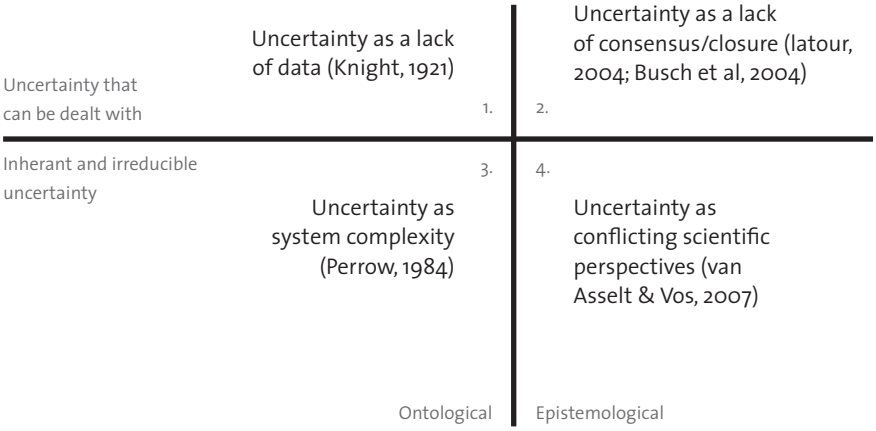

Figure 2 Types of uncertainty (source: authors)

31 See: Harry M Collins and Trevor Pinch, *The Golem: What You Should Know About Science* (Cambridge University Press 2012); Thomas Kuhn, *The Structure of Scientific Revolutions* (University of Chicago Press 1962); van Asselt (n12).

2.3 Risk Assessment, Risk Management, and the Politicisation of Science

After the relevance of assessing uncertainties in the process of dealing with manufactured risk has been considered, it is pertinent to examine the mechanism put in place to regulate risks at the WTO level. The current approach pre-establishes a clear-cut distinction between the assessment of risk and its management. Indeed, "[...] the SPS Agreement al ows countries to set their own food safety and animal and plant health standards. At the same time, however, the SPS Agreement requires that such regulations be based on science [...]".[32] This model of risk governance, known as the 'red book model', reasserts the divide between politics, pertaining to the realm of human world and its subjectivity, and science, which focuses on the discovery of the 'natural' world and the unveiling of 'facts'.[33] This structure, which apparently shields the process of risk assessment from the 'values' present in the risk management, is conducted with the assumption that 'good' science is on nobody's side.[34]

However, as pointed out by B. Latour in his book *Politics of Nature*, the distinction between risk assessment and risk management, or between 'facts' and 'values', is highly problematic.[35] The notion of 'fact' is principally troublesome, as it is believed to refer to a closed category of undividable elements, whereas, in reality 'facts' are the *result* of scientific practice. The construction of 'facts' requires, on the one hand, data to be obtained, and on the other, their arrangement into a meaningful structure. In the process of data gathering, both advanced tools (e.g. cutting-edge technologies, expensive laboratories, etc.) and selected methodologies are essential. Once data is collected, a careful selection of significant information takes place.[36] In this respect, the production of preliminary data is the result of complex networks composed of both, human (scientists, engineer, etc.) and non-humans actors (technologies, laboratory, field trials, etc.). Important to add that the notion of 'fact' also ignores the view that isolated facts have neither significance nor

32 WTO, 'Introduction to the SPS Agreement' <http://www.wto.org/english/tratop_e/sps_e/sps_agreement_cbt_e/c1s1p1_e.htm> accessed 14 May 2014.

33 Erik Millstone, 'Science and decision-making: Can we both distinguish and reconcile science and politics?' in Marjolein van Asselt, Ellen Vos and Michelle Everson (eds), *Trade, Health and the Environment: The European Union Put to the Test* (Routledge 2013).

34 ibid.

35 Latour (n26). In *Politics of Nature*, B. Latour does not use the terminology of 'risk assessment' and 'risk management' but rather of 'facts' and 'values', however the authors believe that the reasoning remains extremely pertinent.

36 For e.g. data might be disregarded on the basis, that it has been contaminated by external factors, or that it provides for no significance in the context of the research.

meaning as long as they are detached from a theoretical framework which is used to put some of these facts together and tie them in a coherent scientific structure.

Values, on the other hand, have the unprivileged position of being considered only after the 'facts' have been established and disclosed. This is caused by the perception that the process of debating values, being a highly subjective endeavour, requires in the first place, to be factually informed. Thus, this artificial divide, which positions values in an unfavourable position, may trigger certain endorsed values to be clandestinely included in the supposedly objective world of things (*i.e.* of 'facts').[37] In the practical world of risk governance, this may results in the inclusion of value judgements in the factual scientific assessment of risk. With time, this artificially strong distinction between the 'facts' and the 'values', between risk assessment and risk management, between experts and risk regulators, will become more and more of a blurred entanglement.

This entanglement is particularly visible in cases of manufactured risk, as, on the one hand, scientific practice cannot provide for authoritative knowledge and, on the other hand, decision makers wish to use scientific knowledge to secure public trust[38] or to legitimise their decisions. This process has been referred to, by M. Everson & E. Vos, as 'the scientification of politics and the politicisation of science'.[39] In this context, and in the light of manufactured risk, different forms of politicisation of science can be identified, among which two are particularly relevant for our case study.

Firstly, science can be politicised through the claim that risk is a 'natural category' and, as such, can only be adequately defined by experts. However, with regard to manufactured risk, scientific knowledge is not in a position to take such stance. Secondly, science can be politicised by limiting the body of recognised scientific evidence. Once the amount of scientific evidence is restricted, a specific interpretation of the data can be claimed to be authoritative and unequivocal.

M. van Asselt and E. Vos identified the attitude of 'uncertainty intolerance' as one of the means through which evidence is being reduced.[40] 'Uncertainty intolerance' refers to the attitude of risk assessors to silence the existence of uncertainties in their risk assessment and/or of risk managers to demand risk assessors to provide them with authoritative

37 Latour (n26).

38 Michelle Everson and Ellen Vos 'The Scientification of Politics and the Politicisation of Scie nce' in Everson and Vos (eds) (n5).

39 ibid.

40 Marjolein van Asselt and Ellen Vos, 'Wrestling with uncertain risks: EU regulation of GMOs and the uncertainty paradox' (2008) 11 Journal of Risk Research 281.

answers that may predetermine a specific regulatory outcome.[41] In the context of the current analysis of manufactured risk, the term 'uncertainty intolerance' refers specifically to situations when particular kinds of uncertainty are being disregarded by risk assessors or decision makers. Once the scientific evidence has been politicised, the scientification of politics generally follows in the form of impeding on the discretion of Member States to set their levels of protection.

3. EC Biotech & Bt-176

In order to assess the politicisation of science when dealing with manufactured risks and uncertainty on a global scale, the *EC-Biotech* case and the dispute concerning the authorization of the GMO Bt-176 maize is significant. The objections brought forward by Canada, Argentina and the United States against the implementation of safeguard measures by the EC Member States reveal the difficulties arising due to the characteristics of manufactured risks. Therefore, it is an essential part of this paper to set the approach of the complaining countries in context with the arguments of the Member States, the evaluation of the Panel, and the defence of the EC.[42]

The various approaches of how modern manufactured risks, as exemplified by Bt-176, and the inherent uncertainty, have been coped with and valued on the national and international levels will be examined. Furthermore, in this case, science had a paramount importance for the WTO Panel to assess whether Member States' sanitary and phytosanitary measures were appropriately based on an assessment of risk.

In particular, as laid down in the Panel report,[43] the complaints mainly concerned two matters. To begin with, the EC's approval procedure for GMO products was claimed to be unfairly constructed, putting the complaining countries' exported products at a disadvantage. Furthermore, safeguard measures maintained by Germany, Austria, and Luxembourg, which imposed marketing restrictions on GM products, were objected as al egedly violating EC's international trade commitments, such as the SPS Agreement.[44]

This paper will focus on this second complaint relating to the safeguard measures established by the EC Member States. Due to the fact that the EC scientific agencies

41 ibid.

42 In the *EC-Biotech* case, the EC acted on behalf of its Member States.

43 Panel Report *EC-Biotech,* para. 2.1.

44 Panel Report *EC-Biotech,* paras. 3.2(a) (United States); 3.4(a) (Canada); 3.6(a) (Argentina).

conducted risk assessments for the products in question and approved them as being safe, the complainants argued that the bans of the Member States could not be sufficiently based on scientific evidence, even though, these safeguard measures were based on scientific studies as well.[45]

As a result, in November 2006, the Panel adopted its decision in the *EC-Biotech* case, ruling in favour of the complaining countries.[46] The WTO Panel found that the safeguard measures applied by Member States constituted an SPS measure,[47] however, they were not based on a risk assessment in the sense of Article 5.1 of the SPS Agreement.[48] Furthermore, the Panel established that Member States failed to comply with the requirements laid down in Article 5.7 to implement precautionary measures.[49] Thus, the EC did not fulfil its obligations under Article 2.2 and 5.5 of the Agreement.[50]

In order to set the framework for the subsequent analysis, a factual description of the Bt-176 maize and its authorization procedure in the EC will be presented in the following section. As already assessed in the conceptual introduction, GMOs, including Bt-176 maize, exemplify the difficulties arising when dealing with manufactured risks since these can only be assessed speculatively. This specific GMO was banned in Germany, Austria and Luxembourg, accepted by the European Communities, and finally assessed by the WTO Dispute Settlement Body in the *EC-Biotech* case. Accordingly, the analysis of Bt-176 maize exemplifies the way science is being politicised in the process of dealing with manufactured risk.

Bt stands for *Bacillus thuringiensis*, a soil bacterium which produces proteins harming specific insect species.[51] Responsible for the production of those proteins is among others the gene Cr1Ab. By inserting it into the DNA of maize plants, the manufacturer confers to the plant a built-in resistance against harmful insect attacks. Bt-176 targets specifically the European corn borer, a crop pest that frequently causes damages to maize in Europe and North America. By cultivating Bt-176, instead of traditional maize plants, significant economic losses in the agricultural sector could allegedly be prevented.

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45 Panel Report *EC-Biotech,* paras. 8.9; 8.10.

46 Gregory Shaffer, 'A Structural Theory of WTO Dispute Settlement: Why Institutional Choice Lies at the Center of the GMO Case' (2008) 41 New York University Journal of International Law and Politics 1, 32.

47 Panel Report *EC-Biotech,* para. 4.155.

48 Panel Report *EC-Biotech,* para. 4.172.

49 Panel Report *EC-Biotech,* para. 8.9

50 Panel Report *EC-Biotech,* paras. 4.175.; 4.176.

51 <http://www2.ca.uky.edu/entomology/entfacts/ef130.asp> accessed 12 June 2014.

Bt-176 was developed by the Swiss pharmaceutical company Ciba Geigy,[52] which in 1994 applied for a market approval for the product in France. French authorities invoked Article 5.6 of Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms,[53] and forwarded the application to the European Commission including a favourable dossier for Bt-176. The dossier was subsequently sent to the Member States' competent authorities, several of which raised safety concerns regarding the product. Accordingly, pursuant to Article 21 of the Directive, the case was transferred to a committee composed of Member States' representatives and chaired by the Commission, where the latter presented a draft decision which had to be adopted by a majority vote. As the committee failed to come to an agreement, the proposal was further submitted to the Council of Ministers, where again a majority vote had to be obtained for the product to be authorized. However, as the Council failed to meet a deadline, the final decision was taken by the Commission.[54]

The Commission requested the Scientific Committee on Animal Nutrition (SCAN), the Scientific Committee on Pesticides (SCPE), and the Scientific Committee on Food (SCF) for an opinion on this subject matter. In 1996, the respective agencies submitted their risk assessments, stating that the Bt-176 could be considered as equally safe when compared to non-GM maize products.[55] Following this assessment, in January 1997, the European Commission authorized the cultivation and marketing of Bt-176 maize in the EU. Shortly after, the French authorities also granted the final approval.

In the same year, Austria and Luxembourg invoked Article 16 of Directive on the Deliberate Release of GMOs, which allows Member States to take provisional restrictive measures regarding products approved by the Commission, provided that there are justifiable reasons to assume that such product poses a risk to human health or the

52 Ciba Geigy in 1996 merged with its competitor, Sandoz, to start a new company - Novartis. In 1999, Novartis and AstraZeneca outsourced their agricultural branches which together formed Syngenta which is now registered by the European Commission as the producer of Bt176.

53 It has later been replaced by 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.

54 Tamara K Hervey, 'Regulation of genetically modified products in a multi-level system of governance: science or citizens?'(2001) 10 Review of European Community & International Environmental Law 321, 322

55 SCAN, *Report of the Scientific Committee for Animal Nutrition on the Safety for Animals of Certain Genetically Modified Maize Line Notified by Ciba-Geigy in Accordance with Directive 90/220/EEC for Feeding Stuff Use* (1996); SCF, *Opinion on the Potential for Adverse Health Effects from the Consumption of Genetically Modified Maize (Zea Mays L)* (1996); SCPE, *Opinion of the Scientific Committee for Pesticides on the Use of Genetically Modified Maize Lines Notified by Ciba -Geigy* (1996).

environment. In April 2000, Germany followed this example. The countries justified their measures by expressing concerns about the safety of gene maize and the scientific uncertainties which, in their view, had not been resolved in the risk assessments.[56] The European expert bodies after examining the reasoning brought forward by Austria, Germany, and Luxembourg concluded that their scientific findings had already been considered in the initial risk assessments, and that no new relevant data had been submitted since.[57] The authorization of Bt-176 eventually expired in 2007, without Syngenta applying for a renewal.[58]

4. Clash of Risk Assessment, Member States vs. EC scientific Agencies

Having provided the necessary conceptual and factual framework, now it will be examined how science is used as a political tool on the European and national levels. In order to do so, the wording of the EC scientific agencies when dealing with Bt-176 maize, the corresponding responses by Member States, as well as the assessment of their arguments by the agencies, will be analysed. Specifically, it this part will examine which types of uncertainity are recognised by the scientists and how these are being dealt with within the context of manufactured risk. Thereby, it becomes clear that by not taking into

56 Bundesministerium für Gesundheit und Frauen, *Gründe für die österreichische Entscheidung, den Gebrauch und Verk auf von gentechnisch verän -derten Maislinien, notifiziert von CIBA-GEIGY in Übereinstimmung mit der Richtlinie 90/220/EWG und zugelassen von Frank reich am 5.2.1997 zu verbieten* (1997) <http://bmg.gv.at/cms/home/attachments/6/2/4/CH1060/CMS1085743089437/bt176-begruendung.pdf> accessed 16 May 2014.

57 SCPE, *Further Report Of The Scientific Committee For Pesticides On The Use Of Genetically Modified Maize Lines* (1997); SCAN, *Report of the Scientific Committee for Animal Nutrition on the Supplementary Question 88 Concerning New Data Submitted by Austrian Authorities on the Safety for Animals of Certain Genetically Modified Maize Lines Notified by Ciba -Geigy in Accordance with Directive 90/220/EEC for Feeding Stuff Use* (1997); SCP, *Opinion on the invocation by Germany of Article 16 of Council 90/220/EEC regarding the genetically modified BT-MAIZE LINE CG 00256-176 notified by CIBA-GEIGY (now NOVARTIS), notification C/F/94/11-03* (2000); EFSA, *Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the Austrian invok e of Article 23 of Directive 2001/18/EC1* (2004).

58 Directive 2001/18/EC which replaced Directive 90/220/EEC includes a provision requiring GMO products to be reauthorized every 7 years. See: GMO Compass < http://www.gmo-compass.org/eng/gmo/db/51.docu.html> accessed 14 May 2014.

consideration some of the uncertainties, the scientists of the EC agencies predetermine politicised outcomes.

The SCAN, SCF, and SCPE, which were consulted by the Commission, concordantly argued for the approval of Bt-176.[59] The evidence these bodies put forward support the assessment conducted by the applicant, Ciba Geigy, who wished to introduce this GMO onto the French market.[60] When comparing these documents with the opinions of Member States, opposing positions regarding how to interpret uncertainty become visible. It has to be acknowledged that Member States had various motivations to restrict the marketing of GMO products. However, as the analysis reveals, they seem to be generally more apt to acknowledge that possible harms caused by new technologies, such as GMOs, cannot be properly anticipated with available scientific data, which is one of the characteristics of manufactured risk.

The diverging standards of Member States and the EC agencies on how to interpret uncertainties becomes visible in their discussion on the risks associated with the antibiotic- resistance gene (*bla*-gene), which had been used as a marker to trace the GM crops. With regard to a possible horizontal transfer of the *bla*-gene to human or animal organisms, potentially causing antibiotic resistance, the SCAN states:

> Another important component in the uptake process is the presence of multimeric forms of homologous DNA sequences at the same binding site on the cell surface. Therefore, in order to have bacterial uptake, multiple copies of the bla gene construct would have to emanate from the plant genome and aggregate at the binding site. These stringent requirements and the overwhelming amount of competitive DNA fragments *make a natural transformation unlikely*.[61] Even under optimal experimental in vitro conditions, a successful transformation has not been achieved.

59 SCAN (n55); SCF (n55); SCPE (n55).

60 A more detailed examination of the risk assessment carried out by Ciba-Geigy would have been interesting for our analysis. However, the corporate affairs office of Syngenta did not reply to our request.

61 Emphasis added.

In its conclusion, the SCAN points out that "[e]xperts agreed that horizontal gene transfer from plant to prokaryotic organisms can be excluded on present scientific evidence."[62] The scientific experts conclude from the low probability that the risk of a transfer can be 'excluded', thus not leaving discretion for varying opinions. This decision indicates that the scientists give meaning to the scientific evidence, thus shaping risk management, and influencing later political decisions.

Meanwhile, the risk assessment carried out by the Austrian *Bundesministerium für Gesundheit und Frauen* (1997) comes to a similar evaluation regarding the probability of the risk:

> On the basis of the present scientific knowledge, the possibility of a transfer of the bla-ampicillin resistance gene to bacteria of the intestine of humans or animals under various conditions which then could cause a harmful clinical impact is very low.

However, the Austrian authorities' analysis of the same examination results in a conclusion which varies essentially from the SCAN's view:

> However from the Austrian point of view especially new scientific results have questioned the present scientific possibility of a conclusive evaluation of the mechanism of gene transfer as well as the development of resistance to the B.t. toxin. Accordingly, possible risks are very hard to assess and should be avoided at the present state of the scientific discussion. Even if the probability of such a genetic transfer is low, the risk of spreading the antibiotics resistance is unacceptable.[63]

The word 'unacceptable' arguably indicates that Austria in this case takes a value-laden decision. However, this document constitutes of the Austrian letter to the Commission justifying their safeguard measures. In this regard, it is not solely a risk assessment, but also

62 SCAN (n55).

63 Bundesministerium für Gesundheit und Frauen (n56).

a part of risk management. A normative stance is therefore not surprising, as the decision-makers are expected to take a decision with regard to the authorisation or ban of the product.

This case demonstrates how the approaches of the European and national risk experts vary significantly regarding the way they deal with uncertainties resulting from a lack of consensus in science. Both SCAN and the Austrian authorities agree that the likelihood of a gene transfer is extremely low. However, the SCAN implies in its conclusion that the product is harmless, while the Austrian authorities consider that this outcome renders the admission of the product 'unacceptable'. They perceive the currently limited scientific knowledge regarding the potential risk as a sufficient reason to invoke precautionary measures.

This viewpoint is reaffirmed in the conclusion of the Austrian opinion:

> [...] the scientific evaluation of possible risks can not be conclusive, as many relevant mechanisms are not fully understood or investigated by now. Furthermore, the highly unlikely risks have to be compared to the fact that high amounts of plant material containing the relevant gene will be given to humans and animals for a long time after an admission of the product to the market. One has also to realise that this product contains the discussed ampicillin resistance gene as well as one more herbicide resistance marker gene which is not any longer state of the art for the production of genetically modified plants. There are adequate maize products already available which do not comprise these restrictions and by this there is no reason to accept risks which are difficult to assess.[64]

The state's authority reemphasises its refusal to take the risk of approving a product whose future impact on health and environment is uncertain. By referring to "many relevant mechanisms [that] are not fully understood", it seems that the Austrian authorities are referring to uncertainty seen as a result of system complexity which cannot be assessed. The scientists of the SCAN, on the other hand, do not acknowledge such uncertainties. Thereby, their action leads to a politicisation of the risk assessment, as the expert body

64 ibid.

implicitly communicates to the risk managers at the European Commission that such complexities are negligible or do not exist. Furthermore, when analysing this paragraph, it becomes apparent that Austria is more sceptical as to whether science can resolve the system complexity in this case. This is particularly evident in the last statement providing that the cultivation of proven and tested substitute products should always be the preferable option.

With regard to the potential antibiotic resistance effect this gene might have on living organisms, the Austrian authorities argue:

> Clearly, degradation and digestion would have to be expected for DNA released from plant material. But recent results show unexpected long survival of DNA under specific conditions (Lorenz and Wackemagel, 1994, Webb and Davies, 1994). Mechanisms of adsorption and release of DNA from particles are not well understood. Specific results indicate that DNA can even pass the gastrointestinal tract without being completely degraded (Schubbert et al., 1994). Proficient information is available about mechanisms and requirements for bacterial competence and transformation in vitro but only limited information is available for the evaluation of these mechanisms and their relevance in specific natural habitats.[65]

And further:

> Also a disadvantage of strains carrying high copy number plasmids has been seen under defined conditions but in a natural situations different selective pressures might be relevant for the establishment of the genetic information.[66]

The Austrian authorities stress that with regard to the potential antibiotic resistance effect in humans or animals, which the spread of the *bla*-gene could trigger, only information

65 See: Oladele Ogunseitan,'Bacterial genetic exchange in nature' [1995] Science Progress 183; Bea Baur, Kurt Hanselmann and others, 'Genetic transformation in freshwater: Escherichia coli is able to develop natural competence' (1996) 62 Applied and Environmental Microbiology 3673.

66 Bundesministerium für Gesundheit und Frauen (n56).

from laboratory studies is available, while the effect under ecological circumstances has not yet been examined. In the author's interpretation, they are concerned with the uncertainty as a result of system complexity in ecological science which cannot be simulated under *in vitro* conditions. In laboratory research, only a limited amount of controllable actions between the studied objects can be included. Whereas, an ecological field study, where the product is tested in the complex natural environment, and where it is almost impossible to predict all possible influences, was not carried out by any of the Member States or agencies.

The German opinion, justifying the country's ban of Bt-176 maize, identified uncertainty in another area.[67] Germany put forward the study of Hansen and Obrycki that found "significant larval mortality of monarch larvae (a butterfly species) fed on host plants exposed to Bt-pollen concentrations representative of those in the field for Bt-176 [A2] and MON810."[68] The SCP in its response to the German measures stated that:

> A number of laboratory studies have been published which have investigated the effects of Bt-modified plants or Bt-toxins in artificial diet fed to the larvae of target pests or other model insect species. Some have reported effects from tritrophic studies of herbivorous larvae and their insect predators or parasitoids whilst others have not detected any significant differences from controls. The implications of such laboratory experiments are very difficult to interpret and extrapolate to the field situation where a wide range of other factors may come into play.

Furthermore, they argued:

> Most recently, Hansen and Obrycki (2000) found significant larval mortality of monarch larvae fed on host plants

67 Unfortunately, we were not able to examine the reasoned opinions which Germany and Luxembourg submitted to the Commissions. Despite sending several emails, the respective national departments did not reply to our requests. Instead, we have retrieved the information regarding the German justification from the reaction document of the SCP (2000).

68 Laura C Hansen and John J Obrycki, 'Field deposition of Bt transgenic corn pollen: lethal effects on the monarch butterfly' (2000) 125 Oecologia 241.

> exposed to Bt-pollen concentrations representative of those in the field for Bt-176 and MON810. However analytical results of toxin levels in the Bt-pollen used in the experiment were variable and differed from the expected toxin levels published elsewhere (EPA 1999a, EPA 1999b).

From this point the SCP scientists concluded:

> The implications of such studies have to be considered against the level of expression of Bt-toxin in pollen of the different Bt-maizes, the local timing and duration of pollen release in relation to the life cycles and development of lepidopteran larvae and the rapid decline of pollen deposition with distance from the source crop. In particular, the interpretation and prediction of effects in the field should be viewed against the comparative risk assessment of alternative crop protection practices and exposure to insecticide sprays. The SCP concludes that the studies cited in the German submission in vitro tests.[69]

The SCP's scientists assessed here the indications for side-effects which could harm non- target organisms and came to the conclusion that the studies treating the subject are complex to assess. In addition, it was expressed that it is difficult to evaluate whether results obtained in the laboratory would also hold valid under field conditions. Additionally, the SCP pointed out that scientific findings were contradictive, and that the work of Hansen and Obrycki stands in opposition to other studies.[70]

While the Austrian concern with regard to system complexity in ecological circumstances has already been discussed, this can also be seen as a case where uncertainty resulting from a lack of consensus is dealt with differently by the parties. On the one hand, the German authorities base their position on a study which points towards potential risks for the monarch butterfly, thereby contradicting the original risk assessment's results that non-target organisms are safe. On the other hand, the SCP

69 SCP (57).

70 Hansen and Obrycki (n68).

refuses to accept this research as a sufficient reason to reject the studies on which the original assessment was based. It is the authors' understanding that, at this point, the two parties interpret uncertainty as a lack of consensus in the scientific community differently. Germany apparently considers that contradicting scientific positions are a sufficient reason to take precautionary measures against the product, while the SCP still upholds the conclusions from the original assessment as correct.

In conclusion, the analysis of the risk assessment documents indicates that uncertainty, particularly as a result of a lack of consensus and system complexity, is interpreted differently by Member States and the scientific studies they refer ,to on the one hand, and the EU expert bodies, on the other hand.

This conflict is however not a matter of 'who knows best', but rather of the two sides' clash on how to deal with these types of uncertainty. Member States seem overall more apt to acknowledge them. In the original risk assessments of the EU scientific bodies, they did not play a role, while in their response to the Member States' concerns uncertainties are mentioned but disregarded, leading to the conclusion that no new evidence has been submitted. As it will be demonstrated in the next part, this position, in conjunction with the WTO Panel's interpretation of the SPS agreement, eventually led to completely disregard the uncertainties presented in the Member States' documents.

5. Disciplining Risk Assessments at the WTO – The *EC-Biotech* case

The World Trade Organization (WTO) is a significant in illustrating tensions among risk definitions as a result of the global aspect of manufactured risks. In theory, it allows Member States to set their own level of protection and, as such, does not conduct risk assessment but only disciplines those conducted by its Members. The WTO requires, through Article 5.1 of the SPS Agreement, that any trade-restrictive regulations be founded on a scientific basis. Such measure must not, in any case, be disguised discrimination or restriction on international trade.[71] However, when the relevant scientific evidence necessary to conduct an adequate risk assessment is insufficient, Article 5.7 allows Members to base their safeguard measures on available pertinent information. However,

71 Article 5.5 SPS Agreement.

the requirements imposed on Members have presented several problems, especially when dealing with the interpretations of these two articles and the key inbuilt concepts thereof, as it will be demonstrated later in this paper.

As presented in the conceptual framework, the politicization of science can occur in different forms: two of which concerning the way risk is being naturalized and the way recognized scientific evidence is being reduced to the extent that Member States no longer have the possibility to freely set their own levels of protection. In this part, it will be demonstrated how the scientific evidence presented by Austria, Germany and Luxembourg in the case of Bt-176 maize is refused legal standing, and how the Panel's reasoning appears to be problematic when dealing with manufactured risk. In essence, scientific evidence can be accepted at the WTO level in three different manners for Member States to base their SPS measures on them. The first consists of being recognized as a 'risk assessment' under Annex A(4) and Article 5.1. The second is by incorporating the evidence presented by the Members to the original risk assessment (in this case: SCP, SCAN & SCF. The third consists of invoking Article 5.7 by proving the existence of the 'insufficiency of scientific evidence'. This part will review how the documents presented by the Member States failed to meet each of the requirements and were ultimately disregarded by the Panel.

5.1 Manufactured Risk

The WTO has developed a few measures which seem to apply within the context of manufactured risk. Even though the originators did not intend this effect, the introduction of Article 5.7 of the SPS Agreement allows the application of precautionary measures[72] in case of insufficiency of scientific evidence. As manufactured risks are speculative and uncertain, this appears to be an adequate provision to deal with them. Furthermore, since not only quantitative risk assessments but also qualitative ones[73] are allowed at the WTO level, it allows in theory a wider range of scientific evidence to be accepted. However, and as will be demonstrated later, these steps are not always sufficient in order to properly tackle manufactured risks.

5.2 Uncertainty

Uncertainty is a complex notion which comprises different aspects, among which four have been emphasized in relation to manufactured risks.[74] In this respect, it is important

72 Appellate Body Report, *EC – Hormones*, para. 124.

73 Appellate Body Report, *Australia-Salmon*, para. 124.

74 See: Conceptual Framework.

to understand the general attitude of the WTO towards the role of science and the types of uncertainty it recognizes. In the *EC-Biotech* case, the SPS Agreement, and the Panel's interpretation thereof, allow for a narrow conception of uncertainty when dealing with the Bt-176 maize. As an ultimate consequence, its interpretation results in the restriction of the Member States' discretion to set their own levels of protection.

It is relevant to look at the way the Panel reacts to the EC's claim concerning the existence of scientific uncertainty in GM crops:

> If scientific uncertainty concerning the risks of biotech plants had been as great as claimed by the European Communities, it is unlikely that any of these products would have successfully completed the regulatory process in any country.[75]

The Panel dismissed the concerns of the EC and its Member States regarding the potential risks of biotech plants on the basis that other countries did not face the alleged uncertainties to complete the regulatory process when approving those products. Such comparison undermines the concerns certain Members have regarding the highly speculative nature of manufactured risks and the potential long-term danger that biotech products have. It thus simplifies the complexity of products which are characterised by their high level of uncertainty.

The perceptions of uncertainty as well as the consequences of such understandings in the context of biotech products wil be referred to in the analyses of the Panel's applications of Article 5.1 and 5.7 with regards to Bt-176 maize.

5.3 Risk assessment – Article 5.1 and Annex A(4) SPS Agreement

In this section, it will be demonstrated how the risk assessment requirements laid down in the SPS Agreement represent a narrow understanding of such assessment for manufactured risks, and triggers several issues. First, the current interpretation of risk assessment leads to the naturalization of risk due to its demand to positively assess the risk through inappropriate legal requirements. Second, these constraints reduce the array of possible outcomes for Member States to decide the risk management policies they deemed necessary.

75 Panel Report, *EC-Biotech*, para 4.538

After declaring that the safeguard measures regarding Bt-176 maize adopted by the Members in question[76] qualified as SPS measures within the meaning of Annex A(1),[77] the Panel decided that it had to first check whether their safeguard measures were 'based on' a risk assessment according to Article 5.1 SPS Agreement. In order to do so, it had to assess whether the documents and scientific studies provided by the Members were actual risk assessments falling under the definition of Annex A(4).[78]

The Panel dismissed the documents and scientific studies provided by the Members because they did not demonstrate the *likelihood* of entry, establishment or spread of a pest or disease or the *potential* of adverse effects on human or animal health arising from the biotech product.[79] For instance, when assessing Germany's Reasons document, the Panel argued that the document provided for the '*possibility*' of risks but failed to evaluate the *'likelihood'* of those risks.[80] Additionally, the document explained that the potential for adverse effects on animal or human health due to the Bt-176 was very small. However, the Panel argued that no clear evaluation of the potential was provided.[81]

In other words, the Panel considered that the Members failed to qualitatively assess the risk. However, only a few paragraphs were dedicated to this dismissal and no concrete evidence of this lack of assessment was given. This blurry interpretation leaves Member States ignorant of the criteria applied by the Panel when the latter considered whether a risk is qualitatively assessed. There seems to be a lack of consistency in this interpretation where the evaluation of *potential* or *likelihood* rests on arbitrary or unclear requirements solely known by the Panel.

Furthermore, when the Panel assessed these documents, the way it used science may be subject to criticism. Firstly, such interpretation of the scientific studies seems to result in the naturalisation of science in the sense that the Panel conceived 'risk' as an objective notion that can, and must, be assessed positively through the use of scientific evidence. As shown above, merely pointing out the possibility and/or the existence of uncertainties

76 Namely Austria, Germany and Luxembourg.

77 Panel Report, *EC-Biotech*, paras. 7.2655 (Austria); 7.2806 (Germany); 7.2915 (Luxembourg)

78 According to Annex A(4), a risk assessment can either be the "evaluation of the *likelihood* of entry, establishment or spread of a pest or disease within the territory of an importing Member" or the "evaluation of the *potential* for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs" (*emphasis added*).

79 Panel Report, *EC-Biotech*, paras. 7.3054 (Austria); 7.3152 (Germany); 7.3208 (Luxembourg)

80 E.g. "adverse effects *would* occur"; "unacceptable development of resistance *may* occur"; "possible effects of Bt-toxin on soil micro-organisms *cannot be excluded*"; etc. (Panel Report, *EC-Biotech*, para. 7.3145)

81 Panel Report, *EC-Biotech*, para. 7.3146.

cannot be considered as a risk assessment under Annex A(4). In these circumstances, the Panel articulates the belief that risk is a natural category that, if existing, must be positively definable through scientific means. Secondly, this view leads to a definition of risk assessment which relies on stringent legal conditions which are hard to fulfil when dealing with manufactured risks. Indeed, *likelihood* and *potential* may not fit the reality of products whose risks are highly speculative. Moreover, these requirements necessitate a positivist assessment of the risks. This means that, in order for the reports to be considered as 'risk assessments', the Members must demonstrate the existence of the risk - even though it is highly speculative. In the present case, since the studies aimed at pointing out uncertainties (which is what is *not* known instead of what *is* known), they were not regarded as risk assessments. Thirdly, by denying scientific evidence which does not assess the potential or likelihood, this restricted perception of what constitutes a 'proper' risk assessment may ultimately lead to a narrow scope of possible outcomes when deciding whether an SPS measure can be implemented in the context of this type of risk. Indeed, Members are left with a reduced capacity to decide by themselves which level of protection they wish to set, based on the available scientific evidence.

5.4 'Based on' a Risk Assessment – Article 5.1 SPS Agreement

In the present section, several points will be made regarding the requirement for a SPS measure to be based on a risk assessment. First, the different types of uncertainty recognized by the Panel will be shown, and the implications of such recognition will be presented. Second, this part will explain the consequences of the Panel's decision that the Member States' divergent views must be explicitly included in the original risk assessment. Finally, the claim that the Members failed to explain how and why they assessed the risks in a different way than the EC agencies will be questioned.

The Panel, after establishing that the documents provided for by the Member States did not amount to 'risk assessments',[82] went on to see whether Austria's, Germany's and Luxembourg's safeguard measures were '*based on*' any risk assessments conducted by the EC scientific agencies. The Panel concluded that the safeguard measures could not be considered to be based on any risk assessments.[83]

82 Within the meaning of Annex A(4) SPS Agreement.

83 Panel Report, *EC-Biotech* case, paras. 7.3086 (Austria); 7.3158 (Germany); 7.3212 (Luxembourg). The arguments presented in the case of Austria's safeguard measure on T25 maize applied *mutatis mutandis* to Austria's, Germany's and Luxembourg's safeguard measures on Bt-176 maize (Panel Report, *EC-Biotech* case, paras. 7.3085; 7.3157; 7.3211).

The EC argued that Members may use divergent scientific opinion based on new information rather than mainstream scientific opinion, and it was so in the present instance.[84] The Panel accepted this claim as it was already established in *EC-Hormones,* wherein the Appellate Body accepted that risk assessments could be based on prevailing/mainstream opinion but also based on diverging scientific views as long as they were from respected and qualified sources.[85] This has been accepted and allowed especially in situations of life-threatening risks constituting a "clear and imminent threat to public health and safety".[86]

However, the Panel pointed out that this was applicable only in cases where the divergent opinion was part of the original risk assessment, which was not presently the case. Indeed, the Panel could not see any divergent views expressed in the agencies' risk assessment.[87] Therefore, the Panel decided that the *EC-Hormones*' decision – that risk assessments can be based on diverging scientific evidence – could not be applied to the current situation. In the Panel's view, safeguard measures based on a divergent scientific opinion could not be based on a risk assessment that establishes a single opinion with no reference to the divergent view.

Previously, the Panel stated that when the Members face a situation where it is possible to conduct a risk assessment because of sufficient relevant scientific evidence, they may take into consideration the uncertainties present in the result and conclusion of the assessment to set their SPS measures. In this context, the risk assessment can support several outcomes and conclusions which may be the basis for different measures. The Panel defines these uncertainties as for example, "uncertainties linked to certain assumptions made in the course of the performance of a risk assessment".[88] However, it seems they can only be relied on if they are explicitly mentioned in the risk assessment.

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84 Panel Report, *EC-Biotech* case, para. 7.3057.

85 "A risk assessment could set out both the prevailing view representing the 'mainstream' of scientific opinion, as well as the opinions of scientists taking a divergent view" (Appellate Body Report, *EC-Hormones*, para. 194).

86 Appellate Body Report, *EC-Hormones*, paras. 193-194.

87 Panel Report, *EC-Biotech* case, para. 7.3059.

88 Panel Report, *EC-Biotech,* para. 7.1525. ("[T]he mere fact that relevant scientific evidence is sufficient to perform a risk assessment does not mean that the result and conclusion of the risk assessment are free from uncertainties (e.g. uncertainties linked to certain assumptions made in the course of the performance of a risk assessment). Indeed, we consider that such uncertainties may be legitimately taken into account by a Member when determining the SPS measure, if any, to be taken. In view of these uncertainties, a given risk assessment may well support a range of possible measures. Within this range, a Member is at liberty to choose the one which provides the best protection to human health and/or the environment, taking account of its appropriate level of protection, provided that the measure chosen is reasonable supported by the risk assessment and not inconsistent with other applicable provisions of the SPS Agreement, such as Article 5.6.")

Additionally, the Panel did not wish to imply that it is impossible to rely partly on a current risk assessment exposing a single opinion, to show divergent opinions. However, it stated that,

> [...] to the extent they disagree with some or al of the conclusions contained in such an assessment, it would in our view be necessary for Members to explain, by reference to the existing assessment, how and why they assess the risks differently, and to provide their revised or supplemental assessment of the risks.[89]

According to the Panel, the Member States failed to do so.

The 'based on requirement' is the second means a Member may implement a safeguard measure at the WTO level. If it did not fulfil the first requirement of Article 5.1 – to have its scientific studies recognized as a 'risk assessment' – it can attempt to show that its SPS measure is 'based on' another existing and recognized assessment, in the present case, the EC original risk assessments.

The first point that can be raised regarding the Panel's decision is that it explicitly recognizes the uncertainty as the lack of scientific consensus[90] as wel as "uncertainties linked to certain assumptions made in the course of the performance of a risk assessment".[91] It thus broadens the scope of recognized uncertainties to tackle manufactured risks in a more adequate manner. However, it has proven to be insufficient and profitless because of the stringency of the legal requirements in Annex A(4) – i.e. potential and likelihood – which render the possibility for Members' scientific reports to be recognized as 'risk

89 Panel Report, *EC-Biotech,* para. 7.3062.

90 Appellate Body Report, *EC-Hormones*, para. 194.

91 Panel Report, *EC-Biotech*, para. 7.1525. ("[T]he mere fact that relevant scientific evidence is sufficient to perform a risk assessment does not mean that the result and conclusion of the risk assessment are free from uncertainties (e.g. uncertainties linked to certain assumptions made in the course of the performance of a risk assessment). Indeed, we consider that such uncertainties may be legitimately taken into account by a Member when determining the SPS measure, if any, to be taken. In view of these uncertainties, a given risk assessment may well support a range of possible measures. Within this range, a Member is at liberty to choose the one which provides the best protection to human health and/or the environment, taking account of its appropriate level of protection, provided that the measure chosen is reasonable supported by the risk assessment and not inconsistent with other applicable provisions of the SPS Agreement, such as Article 5.6.")

assessments' onerous. Thus, if the Members do not pass the first hurdle of proving the potential or likelihood of the risks, they are unable to take advantage of the other types of uncertainty acknowledged by the Panel.

Secondly, it is interesting to see that the Members' different interpretation of scientific evidence and their additional scientific information would only be recognized if they were *explicitly* included in the original risk assessment on which they wish to base their safeguard measures. Indeed, the Panel stressed the fact that diverging views and uncertainties regarding the result or conclusion of the risk assessment must be mentioned in the original assessment for them to rely on. However, since the scientific agencies did not recognize that the documents provided by the Members submitted for additional scientific information, even though they recognized its validity in itself, the measures were deemed not to be based on the original assessment but rather on their own modified and divergent assessment. The agencies did not include any divergent views which could have represented the Members' concerns regarding the potential risks linked to the marketing of Bt-176 maize. The issue with the requirement that the Members' scientific findings must be included in the original assessment for them to be recognized, is that it leaves a very slim possibility for Member States to have their evidence accepted since the agencies' risk assessments are politicized, as previously demonstrated.

Finally, the Panel stated that the Members should have explained how and why they assessed the risks differently compared to the way they were assessed by the EC agencies since they fundamentally disagreed with the original assessment. It is questionable whether they did not do so since they provided for documents and scientific studies that show the possibility of potential adverse effects Bt-176 maize has on human or animal health and the environment.[92] They attempted to show, based on scientific evidence from a divergent source, that the risk assessments conducted by the agencies were not free from any challenge. This is even more striking in the case of Luxembourg, where the Reasons document explicitly refers to scientific information provided by the EC scientific committees.[93] The EC committees acknowledged the fact that, when using Bt-176 maize, the risk that antibiotic resistance would develop because of the gene transfer to bacteria in the gut of humans or animals existed, though small. However, the EC scientific experts dismissed this potential adverse effect due to its low chance of manifestation whereas the Luxembourg authorities were concerned by its possible occurrence.[94]

92 See: Risk Assessment – Article 5.1 and Annex A(4) SPS Agreement.

93 Panel Report, *EC-Biotech*, para. 7.3203.

94 Panel Report, *EC-Biotech*, para. 7.3203.

5.5 Insufficiency of Scientific Evidence – Article 5.7 SPS Agreement

In the following section, Article 5.7 and the Panel's interpretation thereof are analysed in the context of the Bt-176 maize. First, the Panel's decision to reject the Members' measures illustrates the fact that the Panel accepted the EC agencies' risk assessments as an authoritative source, even though they were already politicized at the EU level. Second, the only type of uncertainty, which can trigger the use of Article 5.7, is uncertainty as insufficiency of scientific evidence. This is a clear manifestation of uncertainty intolerance as other types of uncertainty are disregarded. This leads to an additional restriction of the number and types of scientific evidence allowed at the WTO level, which is provided by the Members. Finally, it will be shown how the Panel's interpretation and application of Article 5.7 ultimately leads to the restriction of the discretionary powers Member States should have when setting their own level of protection.

1. Uncertainty as insufficiency of scientific evidence

After holding that the Members' measures regarding Bt-176 maize did not comply with Article 5.1, the Panel examined whether Article 5.7 could be triggered. The Panel found that the safeguard measures did not respect the first condition, which requires the measure to be imposed in respect of a situation where "relevant scientific information is insufficient".[95] Before analysing the Panel's interpretation, it is first important to refer to the definition given by the SPS Agreement regarding the only type of uncertainty which may trigger the use of precautionary measures. As stated in *Japan-Apples* by the Appel ate Body, "the application of Article 5.7 is triggered not by the existence of scientific uncertainty, but by the insufficiency of scientific evidence".[96] Thus, the SPS Agreement allows for the possibility to rely on uncertainty *as lack of data* to avoid the requirements for a risk assessment laid down in Article 5.1 and hence to use provisional measures under Article 5.7.

2. The Panel's definition of insufficiency of scientific evidence

The Panel reviewed the arguments of the EC to see whether there was indeed a case of insufficient scientific evidence. The Members' measures, when submitted to the EC, were reviewed by the EC scientific agencies[97] in order to check whether, on the basis of the information provided by the Members, there was a risk for human health or to the

95 Appellate Body Report, *Japan – Agricultural Products II*, paras. 89 and 176; Panel Report, *EC- Biotech,* para. 7.3218.

96 Appellate Body Report, *Japan – Apples*, para. 184.

97 Germany: SCP; Austria & Luxembourg: SCF, SCAN, SCP.

environment. However, the agencies did not consider that the information provided was 'new scientific evidence' that would overturn the risk assessment that had previously been conducted by the EC agencies.[98] The Panel deemed that the agencies had "*effectively reviewed* their original risk assessment in the light of the information presented"[99] by Germany and came to the conclusion that their risk assessments were still valid and were not altered in any way. The opinions by the EC scientific committees which were expressed for the EC approval procedures (i.e. the original assessments), as well as the opinions by the EC scientific committees which were delivered after the adoption of the Members' SPS measures (i.e. the review assessments) were considered by the Panel as risk assessments within the meaning of Annex A(4) and Article 5.1. Therefore, in the Panel's view, the EC did not prove that the safeguard measures were adopted due to a lack of scientific evidence since the review assessments and the original assessments of Bt-176 maize showed that, at the time the SPS measures were adopted, there was sufficient scientific evidence to conduct an adequate risk assessment within the meaning of Annex A(4) and Article 5.1.[100]

Some remarks can be made regarding the Panel's decision. Firstly, the new evidence presented by the Members was solely assessed by the scientific agencies. The Panel did not take the active position of examining whether the evidence delivered by the Members could overturn the original risk assessments. It neither has the competence nor the scientific expertise to do so, and it is not argued here that it should be given such competence. However, by doing so the Panel accepts the scientific agencies' risk assessments as authoritative sources, even though they disregarded the uncertainties mentioned in the Members' Reasons documents, thus politicizing science and demonstrating a certain level of uncertainty intolerance at the EU level, as previously demonstrated.

Secondly, it is interesting to point out that only the insufficiency of scientific evidence can trigger the use of precautionary measures at the WTO level. Both uncertainty as lack of consensus and as inherent to scientific practice,[101] which are the epistemological categories intrinsic to the scientific practice, are disregarded and cannot be used to trigger the application of Article 5.7. On the other hand, it is worth noting that Article 5.1 recognizes uncertainty as lack of consensus as a sound basis for SPS measures.[102] By disregarding the

98 Panel Report, *EC-Biotech*, paras. 7.3272 (Austria); 7.3326 (Germany); 7.3368 (Luxembourg).

99 Panel Report, *EC-Biotech*, para. 7.3326, emphasis added.

100 Panel Report, *EC-Biotech,* paras. 7.3272 (Austria); 7.3327 (Germany); 7.3369 (Luxembourg).

101 See: the *Conceptual Framework*.

102 "[a] risk assessment could set out both the prevailing view representing the 'mainstream' of scientific opinion, as well as the opinions of scientists taking a divergent view" (Appellate Body Report, *EC- Hormones*, para. 194).

other types of uncertainty, the Panel presents an 'uncertainty-intolerant' behaviour when dealing with these biotech products. Moreover, because other types of uncertainty are not allowed in Article 5.7, the SPS Agreement and the Panel's interpretation contribute to the continuing politicization of science and to the growing diminution of scientific evidence witnessed at all levels (EU and WTO).

Thirdly, the Panel rejected the EC's argument that the assessment of the risk of the Bt-176 maize was concluded in a situation with insufficient evidence. It argued that because the original assessments have successfully been conducted, it proves there was indeed enough scientific data to perform a risk assessment. In the case of Germany Bt-176 maize, the SCP, when reviewing the German Reasons document and other scientific reports, stated that the findings of Germany "do not invalidate the original risk assessment".[103] The Panel interpreted it as implying that no new scientific evidence was provided by Germany that could overturn the risk assessment conducted by the SCPE.[104] It thus confirmed the original risk assessment and demonstrated, in the Panel's view, that there was enough scientific evidence to conduct a proper risk assessment.[105] Therefore, on one hand, the SCP accepted the claim made by Germany but did not include it in the original risk assessment, and on the other hand, the Panel interpreted the SCP's remark that Germany's documents "do not invalidate the original risk assessment" as a proof of sufficiency of scientific evidence.[106] Thus, the agencies disregarded the Members' assessments while recognizing that their information was valid. This resulted in the fact that their scientific documents could neither be recognized through Article 5.1 when basing their SPS measure on the original risk assessment, nor through the application of Article 5.7 by proving insufficiency of scientific evidence. Hence, it appears that the Members' concerns that a low level of risk may materialize were dismissed solely because the EC's original assessment disregarded uncertainties, which it deemed immaterial.[107] This is a direct implication of the

103 SCP (n57).

104 Panel Report, *EC-Biotech*, para. 7.3326.

105 Panel Report, *EC-Biotech*, para. 7.3327.

106 SCP (n57).

107 "In the Reasons document, Luxembourg alleges that Bt-176 maize poses risks in relation to the development of antibiotic resistance and the development of insect resistance to Bt toxin. Regarding the development of antibiotic resistance, the Reasons document refers to scientific advice from EC scientific committees and other scientific experts. *Although Luxembourg acknowledges that these experts indicated that there was only a small risk that antibiotic resistance would develop due to gene transfer to bacteria in the gut of humans or animals, Luxembourg insists that a small risk exists, notably in situations where the maize in question is used as animal feed*, and argues that there is a need for further study regarding the mechanism of gene transfer."(Emphasis added). Panel Report, *EC-Biotech*, para. 7.3203.

politicization of the EC original risk assessments, which results in the dismissal of certain scientific evidence based on certain types of uncertainty, disregarded in the application of Article 5.7. It ultimately leads to the curtailment of scientific information and to the reduction of the discretionary scope Members should have when setting their own level of protection.

5.6 Final Remarks

The analysis of the *EC-Biotech* case attempted to demonstrate the general tendency of the SPS Agreement and the Panel to naturalize risk in the present case. One of the consequences of such form of politicization of science is the ever-continuing reduction of scientific data. Even though some types of uncertainty are explicitly recognized, the Panel did not al ow the Member States' scientific evidence to be given legal standing at the WTO level. While uncertainty as lack of scientific consensus and general uncertainties found in scientific assumptions[108] are accepted when performing a risk assessment, it has been shown not to be useable when legal requirements are too harsh to be complied with. Additionally, these types of uncertainty, although acknowledged by the agencies as well, were disregarded when the scientific agencies stated that the Members' scientific studies did "not invalidate the original risk assessment"[109] and when the Panel interpreted such statement as meaning that diverging views were not expressed in the original risk assessments. Moreover, the application of Article 5.7 can only be triggered by the insufficiency of scientific evidence, which thus disregards the other types of uncertainty. Compartmentalizing the different forms of uncertainty in the application of the different articles and rejecting others denies the possibility of acknowledging the complexity Members and other actors may face when dealing with manufactured risks. Therefore, the legal existence of the certain types of evidence is not recognized due to the restrictive bases on which scientific evidence can be accepted at the WTO level, and due to the restrictive acknowledgment of the different forms of uncertainty.

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108 Panel Report, *EC-Biotech*, para. 7.1525. ("[T]he mere fact that relevant scientific evidence is sufficient to perform a risk assessment does not mean that the result and conclusion of the risk assessment are free from uncertainties (e.g. uncertainties linked to certain assumptions made in the course of the performance of a risk assessment). Indeed, we consider that such uncertainties may be legitimately taken into account by a Member when determining the SPS measure, if any, to be taken. In view of these uncertainties, a given risk assessment may well support a range of possible measures. Within this range, a Member is at liberty to choose the one which provides the best protection to human health and/or the environment, taking account of its appropriate level of protection, provided that the measure chosen is reasonable supported by the risk assessment and not inconsistent with other applicable provisions of the SPS Agreement, such as Article 5.6.").

109 SCP (n57).

The reduction of scientific evidence from one level (EU) to the other (WTO) has two main consequences: first, it leads to a scientification of politics in the sense that it impedes Member States to exercise their discretionary powers by setting the level of protection they deem appropriate. Second, it fails to properly respond to the challenges of manufactured risks, characterized by their global effects, their uncertainties and the speculative nature of their risks.

6. Conclusion

In this paper, we have investigated how science has been politicised in the risk assessment of the EC scientific agencies and in the *EC-Biotech* case concerning the regulation of the Bt-176 maize. In particular, the authors have identified two main forms of politicisation that highly contributed to the regulatory outcomes.

First, the risk of the genetically modified products considered in the *EC-Biotech* case was politically framed by the Panel as a natural category which could be defined on the sole basis of scientific knowledge. This is particularly visible in the requirements expressed in Article 5.1 and Annex A(4) of the SPS Agreement and the Panel's interpretation thereof, which require the SPS measures to be appropriately based on an assessment of risk, and that, such risk assessment must be grounded on scientific evidence that evaluate the potential and likelihood of the risk. In this respect, not only is risk being naturalised, but, in addition, it is considered that an appropriate definition of risk can be positively expressed.

Secondly, we have demonstrated that science is being politically used with the expectations that it could provide for a single authoritative answer. This process takes place at the EC scientific agencies in a risk assessment that does not display the uncertainties that the experts are being faced with,[110] and through the scientists' normative interpretations of the outcomes of their research.[111] At the WTO level, the apparent authoritative power of scientific evidence is the result of the limited amount of evidence[112] that is recognised by the Panel. The process of discounting scientific evidence

110 Particularly visible in the way system complexity is not being mentioned by the EC Scientific agencies while being raised in the Member States reason documents.

111 This is for instance visible when the experts from the SCAN claimed that "[...]a natural transformation is *unlikely* [...]" in their assessment while concluding "that horizontal gene transfer from plant to prokaryotic organisms can be *excluded* on present scientific evidence" (emphasis added). See: SCAN (n55).

112 As well as to the fact that this evidence, namely the EC scientific agencies' risk assessments, has previously been politicised.

is particularly visible through the way most types of uncertainty are being disregarded in the SPS agreement and their interpretation by the Panel. In this regard, in order to adequately evaluate the way science is being politicised, it is relevant to consider which types of uncertainty are being recognised, and in which context.

	EC scientific agencies		WTO, *EC-Biotech*		
	Explicitly present in the risk assessments carried out by the European scientific agencies	Recognised by the EC-Agencies in the responses to the Member States opinion1	Definition of risk assessment according to article 5.1 & Annex A(4)	Available to be used to base member state's safeguard measures on the original EC- risk assessment (Article 5.1)	Can trigger Article 5.7
Lack of data	No	No	Directly triggers Article 5.7	Directly triggers Article 5.7	Yes
Lack of consensus	No	Yes	Yes	Yes	No[1]
System complexity	No	Yes	Ø	Ø	Ø
Inherent uncertainty	Ø	Ø	Ø	Ø[1]	No

Table 1 Types of Uncertainty in the EC scientific agencies risk assessment and in the *EC-Biotech* case.

At the level of the EC scientific agencies, it is relevant to notice that no reference to 'lack of data' could be identified. However, this is hardly surprising considering that lack of data, as understood by the WTO Panel, amounts to the impossibility to conduct a risk assessment based on the available information. Since the experts concluded their risk assessments, and responded to the Member State's documents, this form of uncertainty is effectively 'dispel ed'. On the other hand, 'lack of consensus' was acknowledged by the SCP when assessing the evidence provided by Member States. However, by claiming that this evidence "do[es] not invalidate the original risk assessments",[113] the uncertainty is, in fact, not integrated in

113 SCP (n57).

the risk assessment. With regard to uncertainty as 'system complexity', Austria pointed out that a 'highly unlikely' risk under laboratory research has to be considered in contrast to the complexity of the natural environment in which it will evolve, and that, in such settings, the uncertainty remain unknown.[114] Whereas the risk assessment conducted by SCAN did not, to our knowledge, respond or refer to the existence of such uncertainty.[115] Finally, none of the documents explicitly referred to a type of 'inherent uncertainty', however, this is, not surprising considering that this form of uncertainty cannot really be problematized by scientists (as it consist of additional scientific evidence).

At the WTO level, it could be observed in the analysis of the *EC-Biotech* case that the 'lack of data' is the only type of uncertainty that may trigger the use of Article 5.7. This is the reason why such form of uncertainty is excluded when deciding whether an SPS measure is based on a risk assessment within the meaning of Article 5.1 and Annex A(4). Whereas 'system complexity' is never mentioned in the Panel Report, uncertainty as an "inherent part of science" is explicitly rejected in the application of Article 5.7. Indeed, in *Japan-Apples*, the Appellate Body stated that "the application of Article 5.7 is triggered not by the existence of scientific uncertainty, but by the insufficiency of scientific evidence".[116] Regarding uncertainty as "lack of scientific consensus", it is interesting to see that even though it was accepted in the performance of a risk assessment,[117] it could not be applied in the present case. The Panel decided that the Member States' safeguard measures could not be based on the original risk assessment conducted by the EC scientific agencies because the scientific views on which they rely to base their safeguard measures were not expressed in the original assessments. Indeed, the Panel interpreted the agencies' statement that the evidence provided by the Members did "not invalidate their risk assessment"[118] as meaning that there was no lack of consensus or diverging views in the original assessments. Through this interpretation, the Member States were deprived of the possibility to rely on minority views to base their safeguard measures.

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114 Specifically the Austrian authorities claimed that: "the highly unlikely risks have to be compared to the fact that high amounts of plant material containing the relevant gene will be given to humans and animals for a long time after an admission of the product to the market". Bundesministerium für Gesundheit und Frauen (n56)

115 SCAN instead claimed that "Even under optimal experimental in vitro conditions, a successful transformation has not been achieved." See: SCAN (n55).

116 Appellate Body Report, *Japan – Apples*, para. 184.

117 Appellate Body Report, *EC-Hormones*, para. 194. .

118 SCP (n57)

In conclusion, the politicisation of science, as described above, ultimately resulted in the scientification of politics, i.e. in the reduction, due to the authoritative use of science, of the discretionary power of Member States to set their levels of protection. Although in the *EC- Hormones* case the Appellate Body clearly stated that Members have the right to set their own levels of sanitary protection,[119] it has been demonstrated in the analysis of the *EC-Biotech* case that the Member States were confronted with a narrow scope of possible solutions. The dismissal of the scientific evidence presented in their documents as well as the interpretation thereof by minority views disabled the application of Articles 5.1 or 5.7 of the SPS Agreement.

Through the narrow interpretation of 'risk assessment' and the way certain types of uncertainty are being discarded, one can see how the Panel's understanding of the SPS Agreement is inappropriate to adequately deal with manufactured risks. It is important to point out that the provisions of the SPS Agreement do provide for more room than what can be expected from the Panel's Report. Indeed, Article 5.1 requires the performance of a risk assessment *appropriate to the circumstances*. This argument has been put forward by the EC which claimed that the Member States' safeguard measures were based on an assessment which was appropriate to the present circumstances.[120] However, the Panel rejected this argument[121] and thus furthered the politicisation of science. Overall, even though some leeway is left for improvements in the interpretation of the SPS Agreement, the way risk is being naturalised and positively defined, as well as the rejection of most types of uncertainty, do not seem to allow the WTO to appropriately deal with manufactured risk. Therefore, it seems necessary to reconsider how existing guidelines can be accommodated to risks bearing the characteristics of manufactured risk.

119 Appellate Body Report, *EC-Hormones* case, para. 124.

120 Panel Report, *EC-Biotech* case, para. 7.3052.

121 Panel Report, *EC-Biotech* case, para. 7.3053.

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GMOs Across the Atlantic

Sacrificing Precaution in the Name of Free Trade?

Christina von Hobe, Marcel Hoß, Franca König, Nils Langensteiner, Yanitsa Maksimova, Riikka Mikkonen, Jasmine Styles, Joanna Switalska

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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]

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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