Transatlantic Differences in GMO Regulation

A Case Study Approach

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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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